University of Portsmouth

Description of outcomes, patient experiences and related costs of care in low back pain patients undergoing chiropractic treatment in the UK

A thesis submitted by

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Abstract

Rationale: The prevalence of low back pain and associated costs to society are high. Despite this, the number of studies investigating observational data on the quality and costs of care in routine health care services, such as chiropractic, is relatively small in comparison to the clinical trial evidence available on the effectiveness and cost-effectiveness of manual therapies for low back pain.

Objective: To document the quality and cost of care in low back pain patients undergoing routine chiropractic care in the United Kingdom.

Design: Prospective single cohort multi-centre study.

Participants: A sample of 120 chiropractors and 421 patients.

Methods: Following the development of a data collection instrument and a pilot study, patients suffering from low back pain were recruited by chiropractic clinics in the United Kingdom. Information was recorded using a patient self-report questionnaire at baseline prior to the initial consultation, and participants were mailed a follow-up questionnaire at three months. Health outcomes, patient experiences of the process and safety of care, and related costs in the intervening three month period were documented.

Results: Four hundred and twenty-one patients formed the baseline sample, and 238 (57%) of these returned the follow-up questionnaire at three months. Statistically significant change scores ($p = 0.0001$) were seen for the health status measures including the Roland-Morris Disability Questionnaire, Bournemouth Questionnaire, EuroQol-5D and bothersomeness scale. One hundred and sixty-eight of 238 (70%) patients reported a clinically significant improvement on the Perceived Global Effect scale, and 73 (31%) of these were considered recovered anytime during the study period using definitions of recovery (i.e. acceptable quality of life, no disability and no pain for a whole month). One hundred and twenty-nine (54%) of patients at follow-up rated chiropractic care for their low back condition as ‘very helpful’. The number of patients rating the process of care (i.e. time and explanations given by chiropractor as well involvement in decisions about care) as ‘very good’ ranged from 157 to 168 (66% to 71% respectively of the patients at follow-up). One hundred and

twenty-five (52%) of patients at follow-up reported adverse events of care (i.e. worsening of their back pain, stiffness, soreness and/or general discomfort immediately or shortly after the chiropractic treatment visits); however, only 13 (5%) of these reported that they were unable to carry on with their usual activities and/or work as a result of these events. On average, the total cost of care was £481.83 (95% CI = 333.17 to 639.42) per patient. Lost productivity resulting from time away from work was the most important contributor to these costs (59.6%). The cost of chiropractic visits was the second most important contributor, which accounted for nearly one-third of total costs (32.8%). Other health care usage including general practitioner visits, medical procedures and diagnostic imaging were responsible for a small proportion of total costs ranging from 0.4% to 1.6%.

Conclusions: This programme of research is the first prospective study conducted in routine chiropractic practice simultaneously documenting information about health outcomes and patient experiences and costs of care. Patients improved markedly within the first three months of care and expressed high satisfaction with the chiropractic treatment and consultation they received. Chiropractic care was relatively safe, with common yet benign adverse events that had little influence on activities of daily living. Taken overall, patients receiving chiropractic care reported improvement at arguably reasonable cost, suggesting this approach to the health care of patients with low back pain be considered in the wider context of health care delivery in the United Kingdom.

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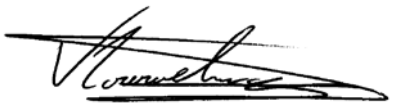
Abbreviations

AECC	Anglo-European College of Chiropractic
AUC	Area under the curve
BQ	Bournemouth Questionnaire
EQ-5D	EuroQol-5D
ES	Effect Size
GPE	Global Perceived Effect
HRQL	Health-related quality of life
IMMPACT	Initiative on Methods, Measurements, and Pain Assessment in Clinical Trials
MCID	Minimal clinically important difference
MCID%	Percent minimal clinically important difference
MCIDr	Raw minimal clinically important difference
MCS	Mean Change Score
MYMOP	Measure Yourself Medical Outcome Profile
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NPA	Negative percent agreement
ODI	Oswestry Disability Index
OECD	Organisation of Economic Co-operation and Development
Picker MSD	Picker Musculoskeletal Disorders
PPA	Positive percent agreement
PSFS	Patient Specific Functional Scale
QALY	Quality adjusted life year
RCI	Reliable Change Index
RMDQ	Roland-Morris Disability Questionnaire
ROC	Receiver Operating Characteristic
SEM	Standard Error of Measurement
SF-36	Short Form-36
UK BEAM	United Kingdom Back Pain Exercise and Manipulation

Declaration

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.



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Dissemination

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LITERATURE REVIEW: CHAPTERS 1-3

Chapter 1 **Patient-reported outcome measures in low back pain**

Chapter 2 **Reporting improvement from patient-reported outcome measures**

Chapter 3 **Assessing cost and patients experiences of care in low back pain**

Preface

Low back pain has a considerable burden on society. According to a survey published in 2000 nearly half the adult population of the United Kingdom reported low back pain lasting 24 hours or more over a 12-month period.[1] The point and lifetime prevalence of low back pain are estimated at 14% and 80% respectively,[2-5] and it is estimated that one in two people who experience low back pain will seek health care for their ailment.[3] In 2006, musculoskeletal conditions were one of the most common reasons for seeking primary care from a general practitioner in the United Kingdom, with the low back being the most commonly affected.[6] In 1998, the cost of health care for all types of low back pain and the cost of lost productivity as a result of this condition were estimated at £1,632 and £3,500 million respectively.[7] Since their publication, these values have likely increased and thus the economic burden of low back pain in the United Kingdom may be even more substantial nowadays.

Despite the high prevalence of low back pain and the associated costs to society, the number of studies investigating observational data on patient outcomes in routine health care services, such as chiropractic, is relatively small in comparison to clinical trial evidence available on the effectiveness and cost-effectiveness of manual therapies for low back pain.[8-11] Similarly, there is a need to measure and analyse data on patient experiences of the process and safety of care so as to determine the adequacy of health care delivery and potential adverse events resulting from the service under consideration.[12] Such data about patient outcomes and experiences are collectively called quality of care indicators and are best measured using data from the patients themselves.[13]

The use of patient-reported instruments has seen an emergence in health care services around the world for the purpose of informing stakeholders, including patients, clinicians, insurers and commissioners, about the quality of care.[14] For example, the Outcomes Framework initiative in the English National Health Service (NHS) uses patient-reported instruments to assess the quality of care for conditions requiring elective surgery, and long term conditions such as diabetes, asthma and chronic obstructive pulmonary disease.[15] The need for this information is vital not

only in public services but also in private settings such as chiropractic clinics providing care for low back pain and other musculoskeletal complaints.

In addition to data about the quality of care, collecting information regarding the cost of that care is imperative due to rising health care costs and limited budgets.[16, 17] The United Kingdom is no exception. Data published by the Organisation of Economic Co-operation and Development (OECD) show that total health expenditure in the United Kingdom rose from £88,490 million in 2003 to £136,439 million in 2009, corresponding to 7.8% and 9.8% respectively of the gross domestic product.[18] A report by the OECD accompanying these figures urges European countries to collect more information about the quality of care and cost of treatment in health care services so as to assist patients and commissioners in choosing providers, thus resulting in more efficient health care delivery.[19]

As a result of the importance of data about the quality and cost of care, there is need to determine this information in all health care service areas. A study of this type assessing the quality and costs of care for low back pain in chiropractic clinics in the United Kingdom has not yet been conducted. The basis of this study was to conduct such an evaluation from the perspective of those patients undergoing chiropractic treatment for low back pain.

CHAPTER 1

Patient-reported outcome measures in low back pain

1.1 Introduction

There is an increasing realisation that diagnostic imaging and laboratory test results as well as objective functional/physiological outcome measures (e.g. range of motion, finger-to-floor and walking distance) should no longer be considered as sole or primary outcomes of treatment in low back pain.[20] Instead the emphasis has shifted to patient self-completed questionnaires evaluating the patient's experiences of the benefit gained on pain, disability and psychological distress as well as other important dimensions of health and quality of life.[14] Such measures, called patient-reported outcome measures, are instrumental in determining, based on factors relevant to the patient, whether additional care is required or whether the patient should be discharged from care and is able to resume a normal working and social life.[21] Moreover, these measures are vital in assessing treatment effectiveness and quality of care from the patient's perspective.[22]

The dimensions of outcome that are most relevant to low back pain patients are likely dependent on a number of factors including socio-demographic and clinical characteristics as well as other individual characteristics such as the patient's coping strategies.[23, 24] This means that, if a comprehensive evaluation of treatment outcomes in low back pain patients is to be made, a range of different instruments must be used. As such, selecting these measures for inclusion in clinical trials and other studies has become an important challenge faced by researchers.[25] One possible approach to this problem is to include a range of different measures in research studies in order not to miss important information. However, this approach is not only time consuming for patients and practitioners, and hence not suitable for clinical research, but also hampers meaningful comparisons between studies.[26] Consequently, there is a need to select outcome measures based on a number of criteria including psychometric properties, relevance and clinical utility. The aim of the present chapter is to offer a comprehensive review of the different types of patient-reported outcome measures in low back pain including those that are used to compare the patients' health status or health-related quality of life at different points in time, i.e. health

status measures, and those that evaluate the course of the condition, i.e. low back pain recurrence and recovery measures.

1.2 Health status measures

1.2.1 Condition-specific measures

Condition-specific measures are designed to evaluate outcomes in a specific disease or population.[27] In 2002, a systematic review conducted by Grotle et al.[28] identified 36 validated condition-specific measures for low back pain. An update of this review reported that this number had increased to 43 between 2002 and 2009.[29] The main construct investigated by these measures was activity limitations, with a few items reflecting various constructs such as pain and symptoms, sleep disturbances, psychological dysfunctions, physical impairments, and social functions.

The overabundance of condition-specific outcome measures available for low back pain reflects the biopsyschosocial nature of this condition.[30] This model of health posits that the pain experience is not only influenced by physical pathology, but also by cognitive-perceptual, psycho-physiological and motoric-environmental factors which are different for each individual.[31, 32] Owing to the complexity of low back pain, and its multi-dimensional nature, capturing outcomes in low back patients remains a difficult task.

In the face of so many outcome measures, and since variability in instruments across studies hinders evaluation of treatment effectiveness and quality of care, the Initiative on Methods, Measurements, and Pain Assessment in Clinical Trials (IMMPACT) recommended that three core health outcome domains should be investigated in clinical trials investigating chronic pain conditions such as low back pain.[33] These are pain, physical functioning and emotional functioning. In spite of these recommendations, however, disability remains the outcome of primary importance in low back pain research. Indeed, the two most frequently used, extensively validated and recommended measures are the Roland-Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI).[25, 28, 34] These are similar assessment tools that measure a patients' perceived level of disability resulting from low back pain.[34] The RMDQ is composed of 24 dichotomous (i.e. yes/no) items that focus on physical disabilities,[35] and the ODI consists of 10 verbal

rating scales that focus on physical disabilities and pain level.[36] Comparative studies have shown that although both measures have similar reliability and validity properties, the RMDQ is most responsive and appropriate in low back pain patients with mild to moderate disability, while the ODI is more responsive in patients with severe disability.[34] Nevertheless, both measures have functioned satisfactorily in settings with differing levels of disability (i.e. physical therapy).[37]

Notwithstanding the importance of assessing disability arising from low back pain, in order to obtain an accurate representation of the patient's health status, there remains the need to evaluate the multi-dimensional aspect of the condition.[30] Although this information could be captured using multiple instruments, such data collection procedures may be time-consuming and may negatively affect patient and practitioner compliance.[38] As a result, in effectiveness and health care quality studies, it may be more practical to use short, concise measures, which nonetheless exhibit the psychometric properties of a valid outcome instrument. Such measures can be classified into two types.

The first is a single question asking about the degree of intrusion of the patient's back pain. An example of this is the bothersomeness scale,[39, 40] which enables patients to incorporate multiple dimensions of outcome in a single question. The second is a multidimensional outcome measure such as Deyo et al.'s core-set[25, 26] or the Bournemouth Questionnaire (BQ),[41, 42] in which a number of dimensions of outcome are assessed, each with a single item. The 6-item core-set, in addition to health outcomes, includes two questions about work-time loss and satisfaction with care.[25] The 7-item BQ, on the other hand, is based on the biopsychosocial model of health and differs from other measures in that it includes questions about the cognitive/behavioural influences in low back pain.[41]

While the bothersomeness scale may be useful in text messaging studies in which the number of characters used is a restriction, this scale may limit comparison between different subjects due to the limited amount of detail it provides.[43] Conversely, multidimensional measures provide information about several dimensions of outcome and may thus facilitate interpretation of health status scores.[26] If greater precision of measurement than can be achieved with a single item for each dimension is required and sufficient resources are available, questionnaires investigating

specific dimensions in more depth (e.g. RMDQ and ODI) may be used to supplement these multidimensional measures.[25]

1.2.2 Health-related quality of life measures

The increasing interest in evaluating health care quality and efficiency has led to the development of a number of generic measures named health-related quality of life (HRQL) measures. These measures allow comparison of outcomes across different interventions and conditions, and can thus be useful in health care policy decisions.[44] Due to this characteristic, HRQL measures are instrumental in cost effectiveness studies, in which the benefit and cost of different interventions can be compared.

Patients ratings in HRQL measures are used to classify patients into a number of health states, which can be converted into a common currency of benefit (i.e. utility score), where one is considered 'full health' and zero or less is considered 'death'.[45] The number of health states depicted by an instrument is determined by both the number of health dimensions and the number of levels within each dimension.[46] The utility scores attributed to these health states are typically obtained through surveys of the general population and, as such, these scores can assist commissioners in making health care policy decisions based on societal preferences.[47]

Owing to their broad scope, generic measures may not measure domains as relevant to the patient with low back pain as those assessed by condition-specific measures.[44] Indeed, comparative studies between both types of measures have shown that the responsiveness and ability to discriminate between improved and non-improved patients is inferior in HRQL measures.[44] Nevertheless, the instrumental role of these measures in health care evaluation studies and their ability to provide a general representation of the patient's health including potential co-morbid features constitutes an advantage over condition-specific measures. Therefore, since health-related quality of life measures may provide a different perspective on health outcomes, it may be useful to combine these measures with condition-specific instruments in outcomes studies for low back pain.[48] In addition, since both approaches have different strengths, the IMMPACT commission suggested that the use of both condition-specific and HRQL measures should be considered in designing chronic pain clinical trials.[49]

A number of validated HRQL measures have been utilised for generic health outcomes determination including the EuroQol (EQ-5D),[50] the Health Utilities Index (HUI),[51] the Quality of Well-Being Scale (QWBS)[52] and the Short-Form 36 (SF-36).[53] Systematic reviews have shown that the EQ-5D and, to a lesser extent, the SF-36 are mainly used in health care evaluation studies for non-specific low back pain.[9, 10] The SF-36 is a 36-item questionnaire assessing six dimensions of general health (i.e. physical function/role, pain, social functioning, emotional health/role and vitality),[54] and the EQ-5D is composed of five questions, each assessing a different dimension of general health (i.e. mobility, self-care, activity, pain and psychological impairment).[50] The popularity of the EQ-5D in low back pain research may be explained by its conciseness compared to its counterparts, and by a recommendation of low back pain experts[25, 49] and guidelines[55, 56] to include this measure in health care evaluation studies. Head-to-head comparisons between the EQ-5D and SF-36 showed that although both measures have good reliability and validity,[50, 54, 57-59] the agreement between the utility scores of both measures is low.[50] This discrepancy may be attributed to differences in scales used, dimensions being assessed and methods used for determining utility scores.[60] Therefore, although both measures use a similar scoring system, only values captured using the same instrument can be compared across different conditions and treatments.

1.2.3 Patient-specific measures

In keeping with the complexity and multi-dimensional nature of low back pain, a recent approach in measuring outcomes in this condition is to evaluate specific symptoms, activities or aspects of life identified by patients to be most affected by the condition.[61] This approach evaluates health status in low back pain patients and patients with other conditions using patient-specific outcome measures which, unlike fixed-item measures such as generic and condition-specific measures, allow individuals to select and rate activities of particular importance.[62, 63] Two measures have been commonly used in research on low back pain, the Measure Yourself Medical Outcome Profile (MYMOP) and the Patient Specific Functional Scale (PSFS).[62] The MYMOP is a self-generated 4-item measure that covers three domains (i.e. symptoms, activity and general well-being),[64] and the PSFS investigates the patient's functional status by asking them to select and rate five activities that are affected as a result of their condition.[65] These measures may address the

idiosyncratic nature of low back pain as patients select functional items of greatest concern and thus may have greater relevance in terms of the different ways in which low back pain affects different individuals.

Since patient-specific measures focus on items relevant to patients, such measures are purportedly more likely to record improvement in outcomes than fixed-item measures.[66] However, this hypothesis is not supported by evidence in group patient data as responsiveness studies comparing condition-specific to fixed-item measures show conflicting findings.[66-70] The reason for this controversy may be that traditional psychometric testing may not be appropriate to instruments with variable item content and thus produce inconsistent results.[63] Since questionnaire items are not standardised, any numeric score may not hold a common meaning and therefore the calculation of statistical parameters using such data is questionable. Another important limitation in patient-specific measures regarding research involving group patient data is that participants require structured guidance to complete these measures, thus making data collection time consuming and costly.[64] As a result, patient-specific measures may not be suitable for quality of care and treatment effectiveness research. Nevertheless, due to their relevance to individual patients, these measures may be useful for monitoring individual outcomes and informing the clinician of an individual patient's progress.

1.3 Low back pain recurrence and recovery measures

A number of cohort studies have demonstrated that low back pain is an episodic or recurrent condition,[71-75] with incidence rates of recurrence following an episode of low back pain ranging from 24% to 33% over 12 months.[74] Estimates suggest that two thirds of back pain related health care and lost productivity costs can be attributed to recurrence of this condition.[76] As a result of these high incidence rates and costs, in addition to measuring patients' health or health-related quality of life at selected points in time using health status measures, documenting recurrence of low back pain in health outcomes assessment is paramount so as to provide additional information about the course of disease.

Although there is a growing interest in evaluating recurrences of low back pain in effectiveness and cost-effectiveness studies, no consensus exists in the literature on

how to define these.[77] Furthermore, if a recurrence means that the patient has firstly recovered from the original episode prior to experiencing a new episode of low back pain, there is a need to define the concept of recovery (i.e. conclusion of an episode before the start of the next). However, there is controversy in the literature regarding this topic as well, with a systematic review reporting over 66 different definitions of recovery.[78] The lack of consistency in definitions used for both recurrence of, and recovery from, an episode of low back pain impedes comparison of findings across different studies. Therefore, the use of standardised measures for these concepts constitutes a priority in low back pain health care research.

In 2011, in a study using a modified Delphi approach, a panel of researchers defined a recurrence of an episode of low back pain as a return of pain in the low back lasting at least 24 hours following a period of at least 30 days pain-free.[79] This definition of a recurrence incorporates the definition by de Vet and co-workers of an episode of low back pain,[80] in which patients are considered recovered if they have been free of low back pain for a period of at least one month. Despite these recommendations, the literature shows differing opinions on the determination of recovery from an episode of low back pain. For instance, Hush et al.[23] identified in a qualitative study on patients' perceptions about recovery from low back pain that, in addition to symptom attenuation such as pain, improved function and achievement of an acceptable quality of life were important determinants of recovery. These authors concluded that it was not only the patient's symptoms attenuation that explained recovery from low back pain, but the impact of symptoms on the patient's ability to perform daily functional tasks and achieve an acceptable quality of life. Conversely, Beaton et al.[81] found that the patient's perception of being recovered from low back pain was not only dependent on resolution of the disorder but also on cognitive appraisal of, and behavioural adaptation to, the pain experience. As such, construct-specific measures (i.e. measures evaluating specific dimensions of recovery such as pain, function and quality of life) may not reflect the idiosyncrasy of the concept of recovery. Measures assessing recovery directly by asking patients whether they perceive themselves as recovered may be more relevant as these measures may enable patients to incorporate any construct into their rating of recovery.[43] The response options on such measures may be binary[82], or in the form of a Likert scale.[83, 84] Notwithstanding the importance of direct reports of recovery, construct-

specific measures may have an advantage over direct reports of recovery in that they may facilitate between-subject comparison as the dimensions affected by low back pain can be identified.[43] Therefore, both direct reports and construct-specific measures may provide useful information in the study of low back pain recurrence and recovery.

Various methods of collecting data about recurrence of, and recovery from, an episode of low back pain have been utilised. These include questionnaires mailed to participants, or telephone interviews conducted, at long time intervals inquiring about symptoms and disability over the follow-up period;[85-87] more frequent inquiries via questionnaires or self-completed diaries;[88-93] and daily follow-up via short messages automatically sent to participants' mobile phones.[72, 73] Each of these methods offers advantages and disadvantages. While data can be collected at frequent time intervals by using self-completed diaries and repeated questionnaires, such methods require co-operation from study participants and may also be relatively expensive.[72, 73] On the other hand, using the short message method may be more convenient for subjects, but the amount of information that can be assessed using this method is often limited. Follow-up at a longer time interval via questionnaire may offer an interesting alternative in assessing recurrence of, and recovery from, an episode of low back pain; however, the data collected using this method relies on the ability of patients to recall information accurately over time. Nonetheless, Stewart et al.[94] found that recall of key parameters of recurrence and recovery (i.e. activity limitation days, and days with pain) showed good correlation with the same data recorded on a daily self-completed diary over a 3-month period. This indicates that patient-reported outcome measures with an extended recall period may provide valid data about low back pain recurrence and recovery.

1.4 CONCLUSION

There is an increasing interest in determining health outcomes using patient-reported outcome measures so as to assist patients and their clinicians in making decisions about treatment as well as commissioners in making informed decisions about health care policy. A number of different measures can be used for outcomes evaluation in low back pain, and each of them has different strengths and limitations. When selecting these measures for use in research conducted in primary care practice, a

number of parameters should be taken into consideration including the relevancy of the information collected and the ease of use, as well as the course of the condition.

CHAPTER 2

Reporting improvement from patient-reported outcome measures

2.1 Introduction

Reporting data from patient-reported outcome measures in a way that is meaningful to clinicians, patients and commissioners of healthcare is equally important as the selection of these instruments. The use of appropriate reporting procedures has important implications for the move towards evidence-based medicine so that data from research studies can be translated to clinical practice.[95] Moreover, these reporting procedures are crucial for the endorsement or rejection of therapies by third party payers or government health plans.[20, 96] Inappropriate reporting procedures could have substantial consequences such as the endorsement of a therapy that in reality is of no clinical benefit to the patient, or the rejection of a therapy that is highly beneficial.

In 2001, Chan et al.[97] reviewed a sample of randomised controlled trials and noted that few authors reported the clinical significance of their results. Moreover, the authors of these studies provided little or no justification pertaining to the methodology that was utilized to determine the clinical significance of their results. In 2007, van Tulder et al.[98] reviewed forty-three studies of exercise therapy for chronic low back pain. Eighteen studies reported conclusions in favour of exercise therapy for chronic low back pain, however, only seven showed a clinically important improvement. Hence, the effect of exercise therapy for low back pain may have been over-reported. Various authors have stated that traditional statistical procedures such as group mean scores and statistical significance of differences between scores on outcome measures are of little use to the clinician and patient.[99-109] For instance, in 2004, a randomised controlled trial funded by the Medical Research Council (MRC) and the NHS, the United Kingdom Back Pain Exercise and Manipulation (UK BEAM) study,[110] concluded that best care plus manipulation plus exercise showed a moderate benefit at three months compared to best care alone.

These conclusions were based upon change scores from the Roland-Morris disability questionnaire that showed a mean difference of 1.87 (95% CI 1.15 to 2.60, $p < 0.001$) in favour of the best care plus manipulation plus exercise group compared to best care alone. Although this net benefit is statistically significant, it is difficult to decide whether participants of best care plus exercise plus manipulation gained any benefit that was of clinical importance.[111] In fact, from the results given in this study, it is not possible to decide if any of the interventions under scrutiny led to a clinical improvement in any of the patients.

Presenting change scores for a therapeutic intervention as group means with statistical significance represented by p-values has several limitations. Firstly, sample variability is not taken into account. It is difficult to determine individual differences from a mean change value. Some patients might have achieved scores well above the mean, others much lower than the mean.[104] Secondly, group mean change values do not provide any information concerning meaning of the magnitude of the change. Thus, it is difficult for clinicians to determine whether the change in scores considerably improved the patient's condition or whether the change in score was in fact too small to be of any benefit to the patient.[100] Lastly, there is no relationship between statistical significance and clinical improvement.[104-106] Furthermore, studies with large sample sizes are more likely to yield statistically significant results.[112] Consequently, a statistically significant difference does not necessarily mean that it is of clinical importance, and vice versa, clinically significant does not imply that the finding is statistically significant.

Traditional statistical procedures are thus unable to show whether patients consider their condition to be clinically improved or not. This information, however, is of major importance to researchers, clinicians, third party payers and most importantly patients themselves. Two papers published in 2006 by Schünemann et al.[112] and Brozek et al.[101] have advocated the use of dichotomization to simplify the understanding of change scores derived from patient-reported outcomes. These dichotomization procedures use threshold values to categorize patients as either clinically improved or non-clinically improved. Any patient or subject below the threshold point is not considered to have undergone a clinically important improvement. The proportion of patients benefiting from treatment can then be calculated for both single-cohort studies and randomised controlled trials. In

randomised controlled trials the net proportion of patients who improved from treatment is calculated by subtracting the proportion of subjects who improved in the placebo or control group from that in the intervention group.[112-114] From this, the number needed to treat (NNT) can be calculated.[111, 115, 116] The number needed to treat, in musculoskeletal research, is the number of subjects needed to treat for one subject to benefit from the therapeutic intervention.

The proportion of patients benefiting from treatment can be determined in two different ways. Both methods require the use of specific thresholds of clinical improvement. Firstly, the proportion of patients who benefit from treatment can be derived directly from global perceived effect scales or global improvement scales. Secondly, the proportion of patients improved can be assessed indirectly from change scores derived from health status measures using threshold values calculated in a number of ways. The aim of the present chapter is to offer a comprehensive review of both methods of determining the proportion of patients achieving benefit from treatment.

2.2 Direct method of measuring improvement using Global Perceived Effect (GPE) scales

The GPE scales can be utilized as a method of determining directly how much the patient perceives his or her condition to be improved. These scales require the patient or subject to state by how much their condition has improved at time points throughout and at the end of the intervention. As such, this method is considered to be a retrospective outcome measure.[117] Conversely, the Bournemouth Questionnaire[41, 118] and the Roland-Morris Questionnaire,[35, 37] for instance, are administered pre- and post-treatment and, therefore, these questionnaires can be seen as prospective outcomes measures.[119] Various GPE scales have been utilized in the literature: Four-point scales: worsened - no change - improved - completely recovered[120, 121]; 5-point scales ranging from ‘much better’ to ‘much worse’[122-124]; numerical rating scales ranging from 0 ‘worst possible state’ to 5 ‘no change’ to 10 ‘best possible state’[125]; and 15-point scales ranging from a ‘very great deal worse’ to ‘about the same’ to a ‘very great deal better’.[126, 127] More recently, however, there has been an emergence of 7-point scales. Commonly, two types have been utilized (Refer to table 2.1). Firstly, a scale that has ‘very much worse’ and ‘very much

better' at the extremes.[128-130] Secondly, a scale showing 'vastly worsened' and 'completely recovered' at the extremes.[83, 131-133] Some authors have decided not to include 'vastly worsened' in the scale because there is no opposite of 'completely recovered'.[131, 134-136]

Table 2.1
Seven point global perceived change scales.

	Scale 1[128-130]	Scale 2[83, 131-133]	
7	very much better	completely recovered	**7**
6	much better	much improved	**6**
5	slightly better	slightly improved	**5**
4	no change	no change	**4**
3	slightly worse	slightly worsened	**3**
2	much worse	much worsened	**2**
1	very much worse	vastly worsened	**1**

The determination of reliability includes both the measurement of internal consistency (Cronbach's α) and test-retest reliability. However, presently, due to methodological reasons these two parameters have not been established for GPE scales. Internal consistency relates individual items of a questionnaire to the total score. However, GPE scales are composed of a single item only and, consequently, internal consistency cannot be measured. The calculation of test-retest reliability would constitute a challenging task as patients would be required to rate global improvement twice for a similar condition with a similar period of improvement. Moreover, the time interval between test-retest sessions would have to be no longer than two weeks.[137]

Physical outcomes and health status measures have shown a relationship with GPE scales and, thus, there is evidence to support construct validity of the latter. Fritz et al.[126] compared the Physical Impairment Index, composed of seven physical tests, with patients' perception of change. The subjects defined as 'unchanged' on the GPE scale showed little variation in Physical Impairment Index scores. Conversely, subjects that categorized themselves as 'improved' showed a steady reduction in impairment scores. Health status measures have shown a similar trend. Patients

categorized as ‘unchanged’ showed little variation in health status change scores whereas patients categorized as ‘improved’ showed substantial decrease in these scores.[83, 126, 127, 129-132] Criterion validity cannot be established because there is no gold standard for patients’ perception of global improvement.[137] The notion of face validity is supported by the fact that it is relevant to ask the patient directly how much his or her condition has improved.

Two studies have investigated patients’ ability to recall their initial health state when using retrospective outcome measures. Norman et al.[117] found that GPE scales were correlated with the present state and uncorrelated with the initial state in prospective outcome measures (i.e. health status measures). From this it was concluded that retrospective outcome measures were affected by recall bias. Middel et al.,[138] in angina pectoris patients, modified each item of the Minnesota Living with Heart Failure Questionnaire (MLHF-Q) into retrospective questions of perceived change. No recall bias was found when retrospective and prospective change scores were correlated with each other. These controversial results may have been caused by the differing concepts measured by GPE scales and prospective outcome measures. Global perceived change scales may measure the patient’s overall health status for several health dimensions including the effects of treatment, side effects and patient expectations.[129]

Despite the utilisation of 7-point Likert scales for the assessment of global perceived change, it is unknown whether Numerical Rating Scales (NRS) and Visual Analogue Scales (VAS) would be more appropriate for its determination. Nevertheless, in pain studies, these three rating methods have demonstrated similar responsiveness.[139-143] Moreover, participants have found 7-point Likert scales to be more user-friendly than their two counterparts.[140, 142-144] Subjects may find a complex 15-point scale difficult to interpret and complete without assistance.[131] Seven-point scales that have no opposite of ‘completely recovered’ are composed of four options for improvement at one extreme, two options for deterioration at the other extreme and ‘no change’ in the centre. Hence, it could be argued that these scales are non-symmetrical. Scales that have ‘very much better’ and ‘very much worse’ at the extremes do not inform the clinician whether the patients’ condition has resolved or not. Therefore, scales that have ‘completely recovered’ and ‘vastly worsened’ at the extremes are suggested (Table 2.1).

Generally, on a 7-point likert scale, category six or 'much better or improved' has arbitrarily been chosen as the threshold for clinically important improvement.[83, 128-130, 132, 135, 136] Therefore, patients that rate themselves as 'slightly improved or better' are not considered to be significantly improved. Ostelo et al.[132] supported their decision to include 'slightly better or improved' in the clinically non-improved group because they found no statistically significant differences between the change scores of the 'slightly improved' category and the 'no change' category. It should be noted that there exists a gap between the categories 'much better or improved' and 'slightly better or improved' (refer to Table 2.1). A study by Bolton et al.[125] showed that the use of an additional category 'moderately better' did not increase accuracy of the threshold for clinical improvement. Moreover, this gap could be considered to be beneficial as it requires patients to decide clearly whether they are clinically improved or not.

2.3 Indirect method of measuring improvement using health status measures

2.3.1 Determination of threshold of clinical improvement using change scores

The threshold of clinical improvement has been named in many different ways in the literature: Minimal Important Change (MIC),[102, 103] Minimal Important Difference (MID),[107, 109, 134, 145] Minimal Clinically Important Difference (MCID),[99, 134, 146] Minimal Clinically Important Change (MCIC)[120, 121, 135, 136, 147] and Minimal Detectable Change (MDC).[120, 121, 135, 136]

An international panel of experts stated that 30% change from baseline may be considered a clinically meaningful improvement when comparing before and after health status scores.[106] Although standardized threshold values may be of use for individual patients, these values may be inappropriate for the determination of the proportion of patients improved. The proportion of patients improved is dependent upon the design and population sample of the study.[103, 107] Two statistical methods have commonly been used to determine the threshold of clinical improvement from change scores derived from health status measures. These are distribution- and anchor-based methods. Distibution-based methods depend on the distribution of the population sample under scrutiny and anchor-based methods are based on an external criterion. Traditionally, GPE scales have been used as the external criterion.

The following distribution based-methods have been used in the literature. Table 2.2 outlines the formula and corresponding threshold of clinical improvement for each distribution-based method. Cohen's Effect Size (ES)[108, 148, 149] is calculated by dividing the group mean change by the group standard deviation at baseline. Different threshold values have been used such as an ES of 0.2, 0.33 and 0.5.[103, 107, 108, 146, 150, 151] The Standard Error of Measurement (SEM)[145, 152, 153] relates the reliability coefficient of the health status measure utilised to the group baseline standard deviation. A wide variety of threshold values have been used in the literature such as a 1, 2 or 2.58 SEM.[103, 123, 145, 150, 154] Some authors have decided to use 1.96 SEM, where 1.96 derives from the 95% Confidence Intervals of no change.[107, 124, 134, 145] Others have used a threshold value of $\sqrt{2} * 1.96 *$ SEM or 2.77 SEM because measurement error can occur twice.[120, 121, 135, 136, 147] The Reliable Change Index (RCI),[105] a derivative of the ES and SEM, has also been used. An RCI of 1.96 has been considered to be the threshold value for clinical improvement.[105, 124, 125, 134, 155]

Table 2.2

Distribution-based method: formula and threshold of clinical improvement.

Method	Formula	Threshold
Effect Size (ES)[108, 148, 149]	$\frac{\text{Mean2 - Mean1}}{\text{SDb}}$	X SD e.g. X = 0.5
Standard Error of Measurement (SEM)[145, 152, 153]	SDb $\sqrt{(1-R)}$	X SEM e.g. X = 1
Reliable Change Index (RCI)[105]	$\frac{\text{Mean2 - Mean1}}{\sqrt{(2\text{SEM}^2)}}$	X $\sqrt{(2\text{SEM}^2)}$ e.g. X = 1.96

SDb: Standard deviation baseline; R: Reliability Coefficient

Several anchor-based methods have been used to derive the threshold of clinical improvement. First, the Mean Change Score (MCS)[99, 146, 156] approach defines the threshold of clinical improvement as the mean change score of patients who selected one or a number of categories on the GPE scale. For instance, van der Roer et al.[136] determined the MCS by using the mean change score of all patients who scored 'much improved' on a 6-point GPE scale. Juniper et al.[127] calculated the MCS by utilizing change scores of patients who rated themselves as '± 2: a little better or worse' and '± 3: somewhat better or worse' on a 15-point GPE scale. A second anchor-based method assimilates change scores from health status measures to a diagnostic test. The GPE scales are used as the gold standard to classify patients as improved or not improved. The ability to diagnose patients correctly as improved (i.e. sensitivity) and the ability to diagnose patients correctly as not improved (i.e. specificity) is calculated for several change scores.[146] The change score that maximizes sensitivity and specificity is chosen as the threshold of clinical improvement. Alternatively, Receiver Operating Characteristic (ROC) curves can be used to identifiy the health status score that maximizes sensitivity and specificity.[103, 134-136, 157, 158]

In 2003, Norman et al.[159] compared thirty-eight studies that determined thresholds of improvement using distribution- and anchor-based methods in patients suffering from chronic diseases. The studies examined resulted in thresholds of clinical improvement that were consistently close to an ES of 0.5. Similarly, one year later Hurst and Bolton[155] showed that an ES of 0.5 could accurately discriminate betweeen clinically improved and clinically non-improved patients suffering from back or neck pain. Norman et al.[159] hypothesized that the ES trend amongst studies may be due to the limits of human discriminability and, therefore, patients could perceive change only beyond an ES of 0.5.

2.3.2 Considerations when using indirect methods to determine improvement

The threshold of clinical improvement determined with indirect methods is dependent on baseline variables. A number of studies have shown that threshold values determined with both distribution- and anchor-based methods were larger for patients with higher pain and disability baseline scores than patients with lower baseline scores.[120, 130, 136] In addition, van der Roer et al.[136] found lower threshold

values in chronic compared to acute patients. The use of statistics to adjust for baseline variables may not necessarily solve the issue as these procedures may not reflect change in a realistic manner.[99, 146]

Distribution-based methods have the advantage of being sample-dependent.[102, 103] Conversely, anchor-based methods are calculated directly from change scores without adjusting for sample variability.[102, 134] In other words, the standard deviation is not taken into account and, consequently, this method might lead to underestimation of the threshold of clinical improvement. Another limitation of the anchor-based methods is the utilization of a retrospective outcome measure to determine a threshold value on a prospective outcome measure. It is presently unknown whether these two outcome measures indeed measure the same concept. Moreover, the use of the GPE scale as a gold standard for improvement has been questioned by some.[117]

Certain distribution-based methods (i.e. the SEM and RCI) are based on the coefficient of reliability of the outcome measure used. Although methods that take into account the reliability of the instrument may appear beneficial, the appropriateness of the coefficient of variation for the determination of the proportion of patients improved is questionable. This parameter is often predetermined in other studies and, thus, may be different for the population sample under scrutiny. Certain authors have attempted to remediate this situation by determining the SEM from within-subject variances of patients categorized as clinically non-improved on the GPE scale.[120, 121, 135, 136] However, the GPE scales have other shortcomings that have been stated earlier in this review.

Norman et al.,[113, 114] using simulation studies, examined the effect of different indirect threshold values on the net proportion of patients improved. The results of the study showed that the choice of threshold value did not influence the net proportion of patients improved. Later in 2007 these findings were confirmed by Lemieux et al. [160] using data from a randomized controlled trial. Lemieux et al.[160] found no consistent difference in the net proportion of patients improved when 0.2 SD, 0.5 SD and 1 SEM were used as thresholds for clinical improvement. There may be several reasons for these findings. First, the threshold of clinical improvement did not take into account individual variations in treatment response. Second, the

threshold values used were unable to discriminate between patients clinically improved and clinically non-improved. Last, the choice of threshold value for the determination of the net proportion of patients improved may in fact not be as important as initially believed. Nevertheless, the real cause is yet to be determined.

Hays et al.[161] demonstrated that threshold values determined with various indirect methods yielded different proportions of patients improved. Consequently, in single-cohort studies, the threshold of clinical improvement may have an impact on the number of patients improved. For instance, a high threshold value could lead to the underestimation of the number of patients improved (i.e. false negatives). Conversely, a low threshold value could lead to overestimation of the number of patients improved (i.e false positives).

2.4 Conclusion

There is a need for data reporting procedures that are relevant to patients, clinicians and other stakeholders in the research evidence. Therefore, studies that collect health data in the practical clinical setting and others may want to include in their methodology the calculation of the proportion of patients improved. It appears that both direct methods using GPE scales and indirect methods using changes scores derived from health status measures can be used for the determination of the proportion of patients improved. Evidence demonstrates that there is convergence between the different methods of achieving the proportion of patients improved. To date it is unknown whether the use of one method is superior to another and, thus, no single method can be recommended. Consequently, it is suggested that patients be categorized into clinically improved and clinically non-improved groups using a selection of procedures composed of a direct method and indirect methods including both distribution- and anchor-based approaches. Moreover, it may be advisable to standardise these procedures to allow comparison of studies assessing similar conditions or treatment interventions.

CHAPTER 3

Assessing costs and patient experiences of care in low back pain

3.1 Introduction

As a result of increasing health care costs and limited budgets, decisions by stakeholders regarding the management of low back pain should not only be based on health outcomes but also on the cost of an intervention.[162] Without such information, patients cannot make a fully informed decision about their care and commissioners cannot allocate resources based on evidence.[163] Therefore, assessing the cost of health care services has become of utmost importance.

In addition to assessing treatment outcomes and costs, it is useful to determine patient experiences of the process and safety of care. Research has shown that satisfied patients are more likely to adhere to treatment, benefit from their health care, and have a higher health-related quality of life. Furthermore, several studies have demonstrated that benign adverse events after manual therapy involving spinal manipulation for low back pain are commonly experienced by patients.[164-168] These patients are typically less satisfied with care and less likely to have clinically important improvements in symptoms and disability compared to patients that do not experience such events.[166] Consequently, the assessment of a patient's experience of care is an important aspect in evaluating the quality of manual therapy services.

This chapter focuses on issues pertaining to the assessment of parameters that complement the evaluation of health outcomes, i.e. costs and patient experiences of care.

3.2 Costs of care

3.2.1 Measuring costs

There are two types of costs: direct costs, i.e. the costs of resources directly related to, and a consequence of, the health care intervention or service under study, such as the cost of consultation and treatment visits, medication, diagnostic procedures and other health care; and indirect costs, i.e. the costs of lost productivity as a result of low back pain or other conditions being investigated.[45] The perspective of the study

dictates the costs included in the analysis.[169] For example, a study conducted from the perspective of the Department of Health does not evaluate the cost of lost productivity. Conversely, an analysis conducted from a societal perspective includes such costs. An analysis from a societal point of view is typically recommended as this constitutes the broadest and most relevant strategy of evaluating costs.[17, 170] Two types of data are needed in order to calculate the cost of an intervention. Firstly, the cost of one unit of each resource (i.e. unit cost), which can be obtained from national cost tariffs, and secondly, the amount of resources used to provide that care.

There are different methods of collecting resource usage data including patient-reported questionnaires and diaries as well as patient records.[171] A drawback of obtaining this information from patient records is the difficulty in accessing these files.[172] Patients may attend a number of different health care services and, therefore, patient records may have to be explored in multiple clinics and hospitals. Moreover, some information such as time off work and over the counter medication cannot be determined using this method.[173] While both direct and indirect costs can be assessed using patient-reported diaries, the amount of patient co-operation needed for their completion is a concern.[171]

Patient-reported questionnaires offer an interesting alternative in assessing resource usage. This method of assessing costs allows determination of a broad range of economic data including lost productivity and out-of-pocket expenses with less effort and resources compared to patient records and patient-reported diaries.[173] However, the accuracy of this type of information relies on the memory of patients and thus may be affected by recall error.

Nevertheless, studies that have assessed the agreement between resource usage data collected from patient records and patient-reported questionnaires have shown conflicting results.[171-177] Some authors reported good agreement and others reported considerable differences between the data collected using these two methods. The reason for this controversy may be that there is no gold standard for assessing health care usage,[172] thus comparing different methods of collecting this information may be questionable. In addition, the accuracy of patient-reported resource usage may be dependent on a number of factors including patient characteristics and number of visits. Indeed studies have shown that elderly patients and patients attending health

care services frequently were less likely to recall the correct number of visits.[174, 175, 177] These findings suggest that older subjects may be more forgetful and that it may be more difficult for patients to recall resource usage with increasing number of visits.[174] Consequently, since the ability to recall resource usage is setting- and population-specific, it may be necessary to report on the accuracy of this information alongside cost results in economic studies.

3.2.2 Analysing costs

Notwithstanding the difficulties in determining costs of care, the analysis of these data can be equally problematic. When information about costs is to be used to inform health care policy decisions, it is the average cost of treatment that is relevant.[178, 179] In economic studies, this figure is presented as the arithmetic mean cost per patient and its associated 95% confidence interval, which is a range of values for the mean that are considered to be plausible for the population under study.[180] In other words, the 95% confidence interval of the mean implies that if a series of studies were carried out repeatedly on different samples from the same population, the mean of these samples would be located within the specified interval in 95 percent of cases.

The traditional or parametric approach to calculating the 95% confidence interval assumes, when a histogram of the distribution of the data is plotted with values on the horizontal axis and frequencies on the vertical axis (an example is provided in Figure 3.1), that data are symmetrically distributed around the mean (i.e. symmetrical or normal distribution).[180] However, cost data typically show a skewed distribution (i.e. non-symmetrical or non-normal distribution),[178] usually due to a high proportion of patients using few health care resources and a minority of patients consuming a large amount of resources (an example is shown in Figure 3.2). Hence, methods of determining the 95% confidence interval that assume normality of distribution may be inappropriate in economic studies.

The bootstrap method has been proposed as an alternative technique to determine confidence intervals in skewed data.[181] This statistical method is a simulation technique in which multiple random samples are drawn from the observed data, with each sampled item replaced after each random draw, and with each sample providing

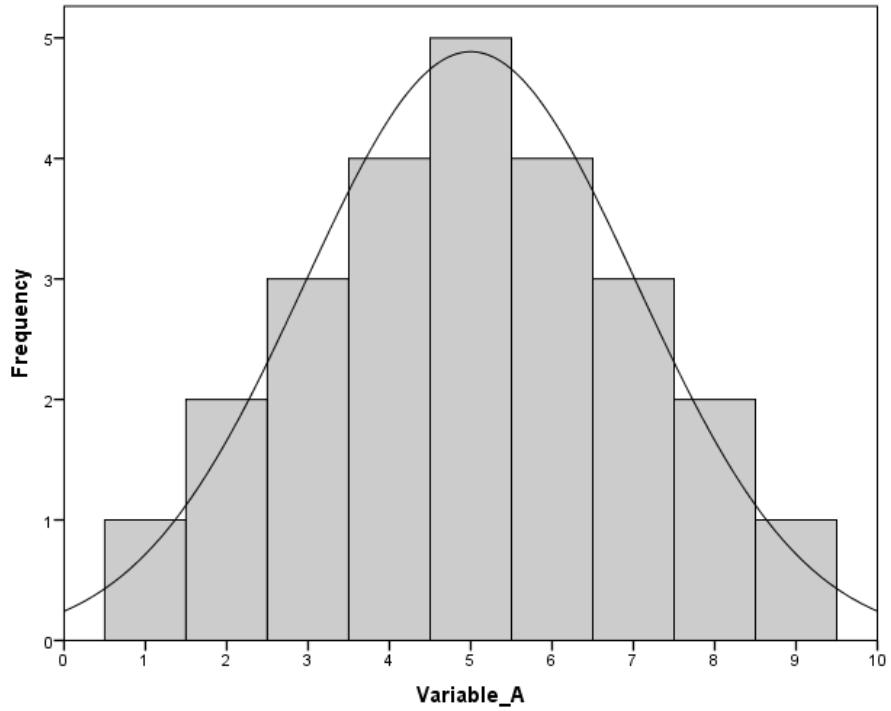

Figure 3.1: Normal distribution in a hypothetical example named Variable_A with superimposed distribution curve.

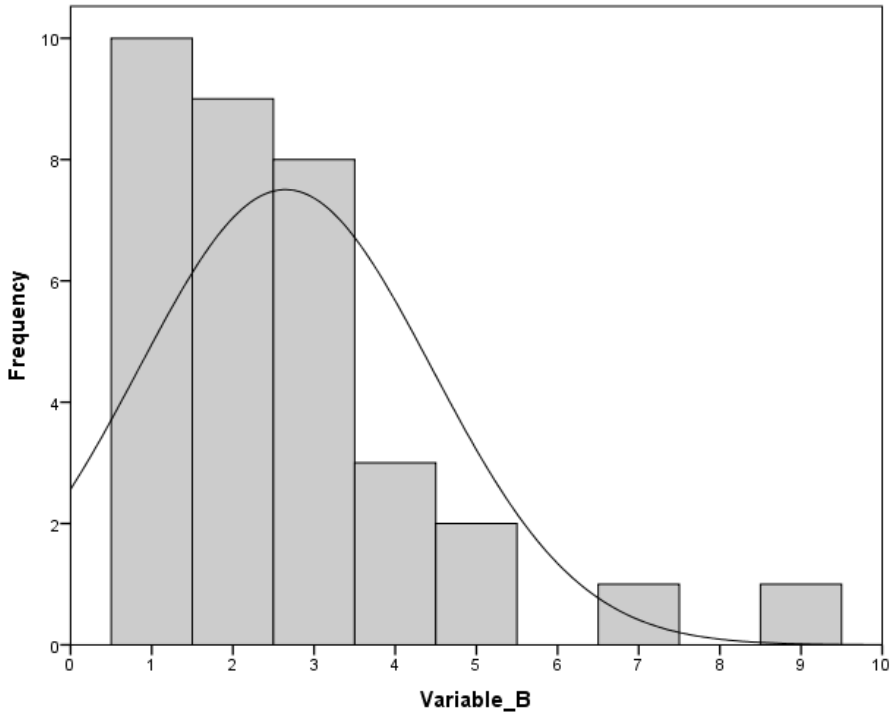

Figure 3.2: Skewed distribution in hypothetical example named Variable_B with superimposed distribution curve.

an estimation of the mean.[178] Repeating the process a large number of times provides information about the distribution of the mean (i.e. bootstrap distribution),[182] thus enabling calculation of its confidence interval. Since the original dataset is considered the parent population in bootstrap analysis, unlike the hypothetical population in parametric statistics, no assumptions are required about the distribution of the data.[183] Therefore, the use of this method is recommended for confidence interval calculation in skewed data such as costs for which parametric assumptions cannot be made.

There are a number of different ways of deriving 95% confidence intervals for the mean from its bootstrap distribution. The traditional percentile method uses the 25th and 975th largest values of this distribution, i.e. the 2.5th and the 97.5th percentiles, respectively, as the limits of the 95% confidence interval.[182] This method, however, is not adequate in cases where the bootstrap distribution is asymmetrical, which is plausible when bootstrap samples are drawn from skewed data.[184, 185] In these instances, confidence intervals may be too narrow and, thus, the bias-corrected and accelerated method of determining the 95% confidence interval is preferred.[184] This method takes into account characteristics of the bootstrap distribution,[185] thus valid bootstrap confidence intervals can be calculated for skewed cost data.

3.2.3 Conducting an economic evaluation

Once cost data have been determined, it is useful to link this information to the consequences of the intervention or service under consideration. It is this link that will allow decisions about the cost of a service to be made. Such a procedure is termed economic evaluation.[186]

Two features characterise an economic evaluation of health care services. First, it deals with the input and output, or the cost and outcomes, of a service, and second, an economic evaluation involves choices.[169] Limited resources, and the consequent inability to meet all desired outputs, necessitates that choices be made with regards to health care services offered.[162, 187] Such choices are made on the basis of many criteria. An economic evaluation provides one set of criteria that may be used to assist commissioners in allocating a limited health care budget.[187]

In order for a choice to be made, there is a need to conduct a comparative analysis of alternative health care services in terms of both the cost and outcomes.[186] Therefore, the basic tasks of an economic evaluation are to determine and compare the costs and consequences of the alternatives being considered. If there is no comparison of alternatives (i.e. evaluation of a single service), the evaluation describes a health care service and is thus termed a cost-outcome description, which is sometimes referred to as a partial economic evaluation.[169] Such an evaluation represents an important intermediate stage in the understanding of the costs and consequences of a health care service. However, a partial economic evaluation cannot assess the efficiency of a service (i.e. cost-effectiveness).[186]

Linking cost and outcomes in a meaningful way is best done by selecting a measure of the benefits of health care services that has a broad applicability, thus allowing for greater comparability.[188-190] The unit of outcome that is recommended by health economists[188, 191] and the National Institute of Clinical Excellence (NICE)[192] is the Quality-Adjusted Life Year (QALY). This measure incorporates both the patient's quality of life, depicted by the utility score attributed to health states from health-related quality of life measures, and the time spent in that state.[191] For example, in an evaluation of a health care service for low back pain, the QALY indicates the patient's quality of life over the period of the study. This contrasts from change scores which measure the difference in outcome (i.e. a subtraction) between two data collection points, thus not taking into consideration the duration of the intervention. Instead, the QALY is calculated by multiplying the utility score associated with a given health state by the duration of time spent in that state.[163]

While the idea of incorporating length of time into the final outcome score has the advantage of simplicity,[190] this concept may not be as relevant to low back pain patients. The use of length of time as an outcome may be informative in the evaluation of treatments that increase life expectancy; however, treatments for low back pain typically do not affect mortality rates.[193] In spite of this limitation, the use of QALYs in economic evaluation of low back pain services is suggested as they allow the outcomes of interventions applied in different disease areas to be compared, thus facilitating resource allocation.[186] In addition, since utility scores attributed to patient ratings on health-related quality of life measures are typically determined using surveys asking the general population to value the importance of

each health state, QALYs enable public participation in health care decision making.[194]

3.3 Patient experiences of care

3.3.1 Patient experiences of the process of care

For many years, the patient's experience of the process of care was assessed using global satisfaction scales (i.e. a scale evaluating the level of satisfaction with care in general); however, more recently, there has been a move towards the use of scales evaluating specific aspects of the process of care.[195] The reasons for this move were that although research showed that global satisfaction was related to ratings of specific aspects of the process of care, specific ratings explained only a small portion of the variation in global satisfaction scores, with factors unrelated to the health system explaining the majority of this variation.[196] In addition, other work conducted in this field demonstrated that over half of the patients that were satisfied with care indicated problems with specific aspects of the process of care.[197] Therefore, since global satisfaction scales offer a limited and optimistic picture, detailed questions about specific aspects of patients' experiences are likely to be more informative in assessing the quality of the process of care.

In spite of the number of instruments assessing patient experiences of detailed aspects of care, only a single questionnaire has been specifically designed for use in patients with musculoskeletal disorders,[198-202] i.e. the Picker musculoskeletal disorders (MSD) questionnaire.[203] This questionnaire may be useful in certain settings; however, the length of this instrument (16 items) is a concern in pragmatic studies in which patient experiences are collected alongside other data such as patient outcomes. In addition, since patient experiences are context-specific and dependent upon the population being studied,[204, 205] the Picker MSD questionnaire may not be relevant to all manual therapy health care services. As a result of the fact that standardised questionnaires cannot be used in all service areas, self-developed patient experiences items have been used to complement outcomes questions in evaluations of health care services for low back pain.[206, 207]

In order for patient experiences questions to be relevant to patients, there is a need to assess the most important aspects of the process of care. Research in this field has

shown that access to care (e.g. facilities, parking, cleanliness), which is so prominent in many surveys, is less of a concern in patients' appraisal of the process of care than receiving adequate explanations, spending sufficient time with the practitioner as well as being involved in decisions about care.[208-210] Having someone show empathy and take the time to listen and explain is a priority for patients.[211, 212] The failure to communicate information about the condition and treatment options is an important source of patient discontent.[213, 214] These findings indicate that the practitioner's attributes are of primary concern to patients and, therefore, questions evaluating patient experiences of the process of care should focus on these.

The number of categories on scales is another issue of importance in measuring patient experiences of the process of care. Garatt et al.[215] compared the shape of the distribution of 5-point versus 10-point scales and found that the use of 10-point scales resulted in non-symmetrical distributions. These findings were due to a tendency for patients to select higher satisfaction scores on a 10-point scale, thus suggesting that patients may be reluctant to use all categories on this scale. Therefore, since 5-point scales performed better than scales with a higher number of categories, the use of the former may be more suitable for assessing patient experiences.

Following the determination of patient experiences of the process of care, these data should be interpreted in a meaningful way. Five-point scales are typically presented with a neutral category in the centre (i.e. 'neither satisfied nor dissatisfied or don't know'), two positive categories at one extreme (i.e. 'satisfied or good' and 'very satisfied or very good') and two negative categories on the opposite extreme (i.e. 'dissatisfied or poor' and 'very dissatisfied or very poor').[207, 216] Evidence from a qualitative study suggests that patients can differentiate between the two positive categories.[217] For some, the category 'satisfied or good' was described as adequate or average, for others it meant that there were aspects of care that could be improved, thus optimal care was not achieved. In contrast, the category 'very satisfied or very good' was described by patients in ways that meant optimal care had been provided. Consequently, distinguishing between both positive categories would be a useful means to interpret ratings of patient experiences and thus understand where future health care could be improved. This may be done by reporting the percentage of patients rating 'very satisfied or good' against all other categories.[217]

3.3.2 Patient experiences of the safety of care

Patient experiences of safety or adverse events of care can be collected in two different ways: reporting by providers through interviews with patients and by patients themselves using patient-reported instruments.[218] While data collected by clinicians are often preferred because of the level of clinical detail that is provided, this method can be time consuming, thus potentially interrupting clinical activities.[219] In addition, clinician-reported methods rely on the clinician's subjective appraisal of the patient's reaction to treatment and may thus not be entirely accurate.[12] Indeed, a study comparing clinician and patient reports of adverse events in hospitals found wide variations between both reporting strategies, with many events that were not documented by clinicians.[219] Similar discrepancies were found in a study comparing both methods of reporting data in acupuncture patients.[218]

The disparities between data about adverse events reported by patients and clinicians may be explained by different definitions of such events. Other reasons include under-reporting by clinicians, perhaps due to concern about medico legal liability, and over-reporting by patients due the use of checklists with tick boxes.[12, 218, 219] As a result of the limitations of both methods of collecting data, different sources of information about adverse events are recommended.

The methods of measuring adverse events are not the only source of variation in results. The definitions used to define such events may also lead to differing findings. Although there is currently no consensus about the best way to define adverse events following manual therapy for low back pain, previous studies conducted by chiropractors, osteopaths and physiotherapists have shown a trend regarding the presentation of such events.[164, 165, 167, 168, 220, 221] These studies found that adverse events were mainly transient and experienced within 24 hours of treatment as well as typically characterised by an aggravation of the patient's complaint or the development of new symptoms such as stiffness, soreness and local or radiating discomfort. In addition, participants reported in a qualitative study that the severity of adverse events was best explained by the impact of symptoms on physical functioning.[222] According to these participants, physical functioning had priority over other factors in evaluating the severity of an adverse event. Hence, questions assessing adverse events could be inspired from the findings of these studies.

3.4 Conclusion

Although the assessment of patient outcomes provides crucial information about the patient's progression in terms of improvement and recovery, it does not supply data about the cost of treatment, nor does it inform stakeholders about the patient's experience of the delivery and safety of care. Hence, patient experiences and costs of care are considered a valuable addition to patient outcomes in performing a comprehensive health care evaluation.

The evaluation of costs enables the attribution of a monetary value to treatment outcomes. Therefore, this information is essential in enabling patients to make informed decisions about their treatment and assist commissioners in allocating resources. However, there are a number of challenges in assessing health care costs, including data collection and analysis as well as linking costs to outcomes in a meaningful way.

Patients' experience of health care, including their opinion about the process and safety of care, is useful in assessing the interpersonal dimension of, and potential adverse events resulting from, the service under scrutiny. Despite the importance of patient experiences in health care, the majority of studies assessing this concept have used self-developed questions, mainly due to the fact that no gold standard exists for its assessment.

RESEARCH PROGRAMMES: CHAPTERS 4-7

Chapter 4 **Research plan**

Chapter 5 **Development of data collection instrument**

Chapter 6 **Pilot study**

Chapter 7 **Main study**

CHAPTER 4

Research plan

4.1 Background

As a result of rising health care costs and mounting pressure to improve the delivery of health care, there is a need to assess the quality and cost of care in all service areas. In the United Kingdom, this information has not been determined in chiropractic clinics for the provision of routine services for patients suffering from low back pain. This is in contrast to the fact that manual therapy has become an increasingly popular therapeutic approach for low back pain, and the number of clinical trials conducted in this field has escalated.

To assess quality and cost of care, the use of a relevant and practical instrument is essential. However, the review of the literature has shown that assessing this information is not only complex but there is currently no comprehensive or standardised patient-reported instrument for low back pain that can simultaneously measure costs as well as the two indicators of the quality of care, i.e. patient outcomes and experiences.

4.2 Aim

The aim of this study was therefore to develop and use an instrument assessing the quality and cost of routine chiropractic care in low back pain patients to inform a range of stakeholders. Collection of data in busy routine practice necessitated a pragmatic approach at the same time as ensuring the instrument was fit for purpose.

4.3. Objectives

The objectives of this study were:

PHASE I - To review the existing knowledge base:

- To select outcomes relevant to patients, clinicians and healthcare purchasers to evaluate low back pain patients undergoing chiropractic treatment, as well as methods to measure these.

- To select methods of reporting outcomes data in ways that are meaningful to stakeholders including patients, clinicians and healthcare purchasers.
- To select patient experiences relevant to patients, clinicians and healthcare purchasers in low back patients undergoing chiropractic treatment, as well as methods to measure these.
- To select methods to measure costs of care relevant to patients, clinicians and healthcare purchasers in low back patients undergoing chiropractic treatment.

PHASE II - To develop an instrument:

- To measure patient-reported outcomes, experiences and related costs of care in low back patients undergoing chiropractic treatment.
- To capture this information in a comprehensive, relevant and pragmatic manner suitable for patients attending a primary care practitioner.

PHASE III - To undertake a pilot study:

PHASE IIIa

- To evaluate the clarity of the documentation.
- To evaluate the feasability of the data collection process.

PHASE IIIb

- To refine the documentation and data collection process based on the results of these evaluations.

PHASE IV - To undertake a main study:

PHASE IVa

- To document outcomes, patient experiences and related costs of care in low back patients undergoing chiropractic treatment.
- To evaluate methods of reporting outcomes data in a meaningful manner to patients, clinicians and purchasers of healthcare.
- To evaluate the data collection instrument in terms of:
    a. Accuracy of patient-reported number of visits made to the clinic.

b. Responsiveness of health status measures.
c. Construct-validity of measuring recovery.
d. Clarity and face validity.

PHASE IVb

- To refine the instrument based on the results of these evaluations.

4.4 Research questions

The reserach questions of this study were:

PHASE I - To review existing knowledge base:

- What outcomes are relevant to low back patients undergoing chiropractic treatment and how are these measured?
- How are outcomes data reported in ways that are meaningful to stakeholders including patients, clinicians and healthcare purchasers?
- What patient experiences are relevant to low back patients undergoing chiropractic treatment and how are these measured?
- How are costs of care that are relevant to patients, clinicians and healthcare purchasers measured in low back patients undergoing chiropractic treatment?

PHASE II - To develop a patient-reported instrument:

- How are patient-reported outcomes, experiences and costs of care measured in low back patients undergoing chiropractic treatment?
- How is this information captured in a comprehensive, relevant and pragmatic manner suitable for patients attending a primary care practitioner?

PHASE III - To undertake a pilot study:

PHASE IIIa

- What is the clarity of the documentation?
- What is the feasibility of the data collection process?

PHASE IIIb

- What refinements can be made to the documentation and data collection process based on the results of these evaluations?

PHASE IV - To undertake a main study:

PHASE IVa

- What are the outcomes, patient experiences and related costs of care in low back patients undergoing chiropractic treatment?
- How can outcomes data be reported in a meaningful manner to patients, clinicians and purchasers of healthcare?
- To evaluate the data collection instrument in terms of:
    a. What is the accuracy of patient-reported number of visits made to the clinic?
    b. What is the responsiveness of the health status measures?
    c. What is the construct-validity of measuring recovery?
    d. What is the clarity and face validity of the instrument?

PHASE IVb

- What refinements can be made to the instrument based on the results of these evaluations?

CHAPTER 5

Development of data collection instrument

5.1 Introduction

Developing a data collection instrument is an important task as it captures the raw data that will be used for the analytical part of a research study. Statistical manipulation cannot be used after data have been collected to compensate for poor content or missing questions. Therefore, all aspects of the condition being assessed should be taken into consideration when questionnaire items are devised.[137]

Notwithstanding the importance of capturing a maximum of relevant and comprehensive information using patient-reported instruments, due to being administered in a clinical setting, the length of such measures is always a consideration. As such, these questionnaires require particular emphasis on practicality and conciseness while at the same time providing an adequate amount of information about each aspect of the condition under study.

The ultimate goal of data collected from patient-reported instruments is to inform patients and researchers, as well as to provide support for healthcare commissioning. Given the importance of these activities, patient-reported measures should be relevant to patients themselves and be supported by published evidence. If validated measures are not available to investigate a domain, care should be taken to find other relevant sources of scientific evidence to support its measurement.[14, 223]

The aim of this chapter is to describe the development of a data collection instrument to measure patient outcomes and experiences, as well as costs of care, for patients with low back pain in routine chiropractic practice.

5.2 Methods

Data collection for the study took place on two occasions; first at baseline before the initial consultation and second at three months. Two instruments, ‘Questionnaire 1 at initial consultation’ and ‘Questionnaire 2 at three months’, were designed to capture the following:

- Patient and clinical characteristics at baseline.
- Patient outcomes at follow-up and in the intervening period of three months.
- Patient experiences of care during the 3-month period.
- Costs of care during the 3-month period.

There were a number of challenges when developing these instruments. Firstly, the questionnaires had to be simple and concise to avoid causing any interruption of clinical activities. To avoid confusion, skip patterns,[224] in which participants are referred to a new section of the questionnaire to avoid items not relevant to them, were not used. Therefore, each question was answerable by all participants. Secondly, since data were not collected during the intervening period from the first (baseline) to the second (three months) data collection point it was challenging to determine the course of the condition, including the pattern of recovery over this time period from a single measure at the end.

5.3 Results

Table 5.1 shows a summary of the items included in the baseline and follow-up questionnaires, which are given in Appendix 1. In the follow-up questionnaire, patients had to recall the progress of their condition over the 3-month period and the questionnaire was designed to take this into account. Patients had to recall how they felt today (the day they completed the questionnaire), in the past week and in the past three months.

Baseline demographic and clinical characteristics, recorded in the baseline questionnaire, were gender, age, employment status, duration of presenting episode of low back pain and medication usage.

Four validated prospective outcome measures were included in the first and second questionnaires. First, the Roland-Morris Disability Questionnaire (RMDQ),[35] which is a disability condition-specific questionnaire for low back pain, second, the Bournemouth Questionnaire (BQ),[41] which is a comprehensive multidimensional condition-specific outcome measure and third, the EuroQol-5D (EQ-5D),[50] which is

Table 5.1

Structure of data collection instrument.

1. **Demographic and clinical characteristics at baseline**
    - Age
    - Gender
    - Work status
    - Duration of presenting episode of low back pain
    - Medication usage
2. **Patient outcomes**
    a. **At follow-up (prospective)**
        - Roland-Morris Disability Questionnaire (RMDQ)
        - EQ-5D
        - Bothersomeness scale
        - Bournemouth Questionnaire (BQ)

    b. **In the intervening period (retrospective)**
        - Global Perceived Effect (GPE) scale
        - Recovery
3. **Patient experiences during the 3-month period**
    a. **Process of care**
        - Satisfaction with care
        - Perceived helpfulness of care

    b. **Safety of care during**
        - Adverse events
4. **Cost of care during the 3-month period**
    a. **Direct costs**
        - Chiropractic visits
        - Diagnostic procedures
        - Change in medication usage
        - Other healthcare usage
        - Disability/incapacity benefits

    b. **Indirect costs**
        - Work time loss
5. **Additional data collected at follow-up**
        - Lifestyle changes
        - Questionnaire feedback

a generic non disease-specific instrument used to value health-related quality of life, and lastly, the bothersomeness scale,[39] which is a single question asking about the degree of intrusion of the patient's back pain. The second questionnaire also included two retrospective outcomes for measurement of the intervening period between the two data collection points. These were Global Perceived Effect[83] and recovery. Patients were considered to be recovered if they are free of low back pain and are able to perform their usual physical and social activities without interference from their back pain for a whole month preceding the second data collection point.[23, 78]

Measures of patient-reported experiences were included in the follow-up questionnaire. These questions measured aspects of the process and safety of care. Patient experiences with the process of care were: global satisfaction with care and perceived helpfulness of care. Safety of care was measured by assessing whether patients had experienced any adverse events and their severity during the 3-month period. In addition, a number of questionnaire feedback items and items about potential lifestyle changes that patients made during the 3-month period were included at the end of the follow-up questionnaire.

Costs over the 3-month period (follow-up questionnaire) were measured from a healthcare and societal perspective. Direct costs were chiropractic visits, diagnostic procedures used, change in medication usage, as well as other healthcare usage and disability/incapacity benefits. Patients were asked to report on the number of treatments received over the 3-month period. Indirect cost to society was taken into consideration as work time loss because of back pain during the 3-month period.

5.4 Discussion

All scales assessing clinical and demographic characteristics except for the duration of the presenting episode of low back pain (i.e. chronicity) were self-developed based on items derived from a number of sources.[85-87, 225-233] The scale assessing the chronicity of low back pain was adopted from the work by Dunn et al.[234] In this qualitative study, the clarity of participants' responses appeared higher using a question asking patients to recall their last pain-free month compared to a more traditional question asking patients to recall the time of onset of their low back pain.

All the included health status outcome measures and the GPE scale have been tested for validity, reliability, and responsiveness and shown to be robust. [34, 35, 39, 41, 50, 59, 235] The RMDQ and EQ-5D, assessing condition-specific disability and generic HRQL respectively, were included in the instrument as they are frequently used in low back pain research, and recommended by low back experts and guidelines.[9, 10, 25, 28, 34, 49, 55, 56] In addition, the BQ and bothersomeness scale were included in the instrument so as to provide data about the multidimensional aspect of the condition, including physical, psychological, cognitive/behavioral and social dimensions of back pain.

A 7-point GPE scale was used with 'completely recovered' at one extreme to determine, in addition to patient's perceived improvement, whether the patient's condition had resolved (i.e. conclusion of an episode of low back pain). The 7-point GPE scale has been widely used in the literature,[83, 128, 132, 133, 138, 236] and has been shown to be as responsive as the more cumbersome 14-point scales.[236]

Questions about specifc aspects of recovery from low back pain (i.e. construct-specific method of determing recovery) were also included in the instrument. In previous research, such questions have been based on the definition by de Vet et al.[78] in which recovery is dependent on pain-free periods. In the present study, in addition to pain, physical function and quality of life were investigated due to participants reporting in a recent qualitative study that these dimensions were important determinants of the concept of recovery from low back pain.[23] The construct validity of this self-developed scale was determined in the main study by comparing patients categorised as recoverd using the construct-specific questions and patients categorised as 'completely recoverd' on the GPE scale (i.e. direct report of recovery).

Patient experiences of the process of care were determined using two 5-point scales assessing global satisfaction with care and perceived helpfulness of care. Such measures have been used extensively in the literature.[208] The scale assessing adverse events, i.e. patient experiences of the safety of care, was self-developed based on existing research about the most common presentation and severity of such events in low back pain patients receiving chiropractic care and other forms of manual therapy.[164, 165, 167, 168, 220-222]

The validity of patient experiences scales is rarely reported in the literature. Since no

gold standard is available for patient-reported measures, validity is usually determined by measuring the degree of closeness of the measure under study to a measure of the same construct (i.e. construct validity).[137] However, measures of a similar construct are generally not available for patient experiences, thus construct validity cannot be determined for scales assessing these.

The scales used to assess all cost variables except change in medication usage were adopted from a randomized controlled trial of acupuncture and usual care conducted for the NHS.[207] The determination of medication usage necessitated a scale that was specifically tailored to the study. Since pain medication for low back pain typically includes over-the-counter medication, it was difficult to determine the exact type or quantity of medication patients consumed during the study. Instead, patients were asked to report on the change in use of medication since the beginning of the study.

Evaluating the validity of cost information is controversial since all methods of collecting these data suffer from drawbacks. For instance, practitioners may inadvertently omit data from patient records and patients may be unable to recall their health care usage. Despite this limitation, the validity of data about number of visits, which is typically the most important source of error in measuring costs, was assessed in a sample of patients from the main study by comparing patient-reported number of visits made to the clinic and the same information reported in patient records.

The relevance of an instrument to stakeholders is dependent on the validity of its content. Content validity is a theoretical concept that refers to the extent to which the content of an instrument appears to comprehensively examine the full scope of the domain it is intended to measure.[237] The data collection instrument included variables assessing all aspects of the quality of care as stated in the document 'High Quality of Care for All'[13] published by the Department of Health. Moreover, the instrument assessed all aspects of the cost of care as stated in the costing report for low back pain published by NICE,[238] which accompanies the guidance for the early management of persistent non-specific low back pain.[239] To provide information about the broader impact of low back pain on society, costs resulting from lost productivity were calculated. As such, the instrument tapped all relevant aspect of the quality and cost of care.

The clarity of an instrument is depicted by the notion of face validity. This concept refers to the participants' subjective assessment of the presentation and relevance of the patient-reported instrument.[137] This was determined by including in the follow-up questionnaire three participant feedback questions about the clarity, length and relevance of the questionnaires they completed.

5.5 Conclusion

A wide range of data was needed for meeting the objectives of this study and, therefore, a comprehensive yet pragmatic instrument was required for data collection. Due to the fact that no standardised measure was available for all constructs under scrutiny, validated measures were included in the instrument when possible, and self-developed scales based on existing evidence were used in all other cases. As such, the final instrument provided information about all aspects of the quality and cost of care in a succinct manner and could thus be used for data collection in the participating clinics.

CHAPTER 6

Pilot study

6.1 Introduction

Collecting data in a pragmatic setting is an uncertain exercise. As a result, following the development of the data collection instrument, in studies using patient-reported data, a pilot study is typically conducted on a small number of patients or participants.[240] A pilot study is a small scale rehearsal of the intended or main research enabling investigators to test the logistics of the data collection process. Any issues arising during a pilot study can be corrected prior or early in the main study's data collection period.[223]

A pilot study can be external or internal. An external pilot study is planned and carried out separately from the main study whereas an internal pilot study is conducted alongside the main study.[240] The advantage of an external pilot study lies in the ability to refine the main study prior to its commencement. Pilot studies should have a well-defined set of aims and objectives to ensure methodological rigour and scientific validity.

6.2 Aims and objectives

The aims of this pilot study were to test and evaluate the methods of data collection including the clarity of the study documentation and feasibility of the data collection process.

The objectives of the pilot study were:

PHASE IIIa

- To evaluate the clarity of the documentation (Appendix 1):
    - Baseline and follow-up questionnaire.
    - Cover letter accompanying data collection pack – for the attention of chiropractors and clinic staff.
    - Cover letter accompanying follow-up questionnaire –

for the attention of participants.

- User guide regarding data collection process.
- Number of patient visits form and accompanying cover letter – for the attention of chiropractors and clinic staff.

- To evaluate the feasibility of the data collection process:

  - Patient recruitment by chiropractors and/or clinic staff.
  - Administration of questionnaires by chiropractors and/or clinics staff.
  - Data storage procedures.

PHASE IIIb

- To refine the documentation and data collection process based on the results of these evaluations.

6.3 Methods

6.3.1 Selection of chiropractors

A convenience sample of four chiropractors who were affiliated with the AECC and listed as members of the British Chiropractic Association for the year 2010 was used for the pilot study. This type of sample was adopted to ease the communication as practitioner feedback was an important aspect of this pilot study. All four chiropractors agreed to participate in the research.

6.3.2 Procedures of pilot study

The pilot study was conducted in clinics between May and June 2010. Data collection took place on two occasions, at baseline (baseline questionnaire) and at three months (follow-up questionnaire). The four participating chiropractors were mailed a study pack containing a cover letter, a user guide, 10 questionnaires and 10 pre-paid envelopes. Approximately five days after this mailing, the pilot practitioners and/or clinic managers were contacted by phone and/or electronic mail to enquire whether the data collection pack had arrived and whether they had any questions regarding the conduct of data collection and related procedures. A written log of

communications with any of the pilot practitioner and/or clinics managers and reflective notes were assembled and continually added to regarding any queries made or problems encountered throughout the study. Following completion of the data collection period, the pilot practitioners were acknowledged via phone and/or email for their involvement. In addition, they were asked: i) whether the instructions (cover letter and user guide) were clear and understandable; ii) whether patients had any issues with the baseline questionnaire including the information and informed consent sections; iii) whether there were any issues with the data collection process in general; and iv) how much time on average was needed for patients to read and complete the questionnaire.

Chiropractors and/or their staff were asked to recruit 10 consecutive new low back patients fulfilling the following inclusion criteria:

- Low back pain with or without leg pain as main complaint.
- Aged 18 years or older.
- No treatment for low back pain from a healthcare professional except from their GP in the past three months.
- Literate in English.
- Women who were not pregnant.

The data collection process is shown in Figure 6.1. Eligible patients were asked to arrive at the clinic 10 to 15 minutes before their initial consultation to allow sufficient time to read about the study and complete the baseline questionnaire. Patients were asked by clinic staff to read the information at the start of the questionnaire and decide whether or not they wished to participate in the study. If patients decided to take part in the study, they were asked to sign the informed consent section of the questionnaire and complete all questions in the document. Once completed, the questionnaire was immediately returned to the AECC in a single pre-paid envelope. If patients decided that they did not want to take part in the study, the chiropractor or clinic staff recorded their gender and birth date at the back of the questionnaire and returned the questionnaire uncompleted.

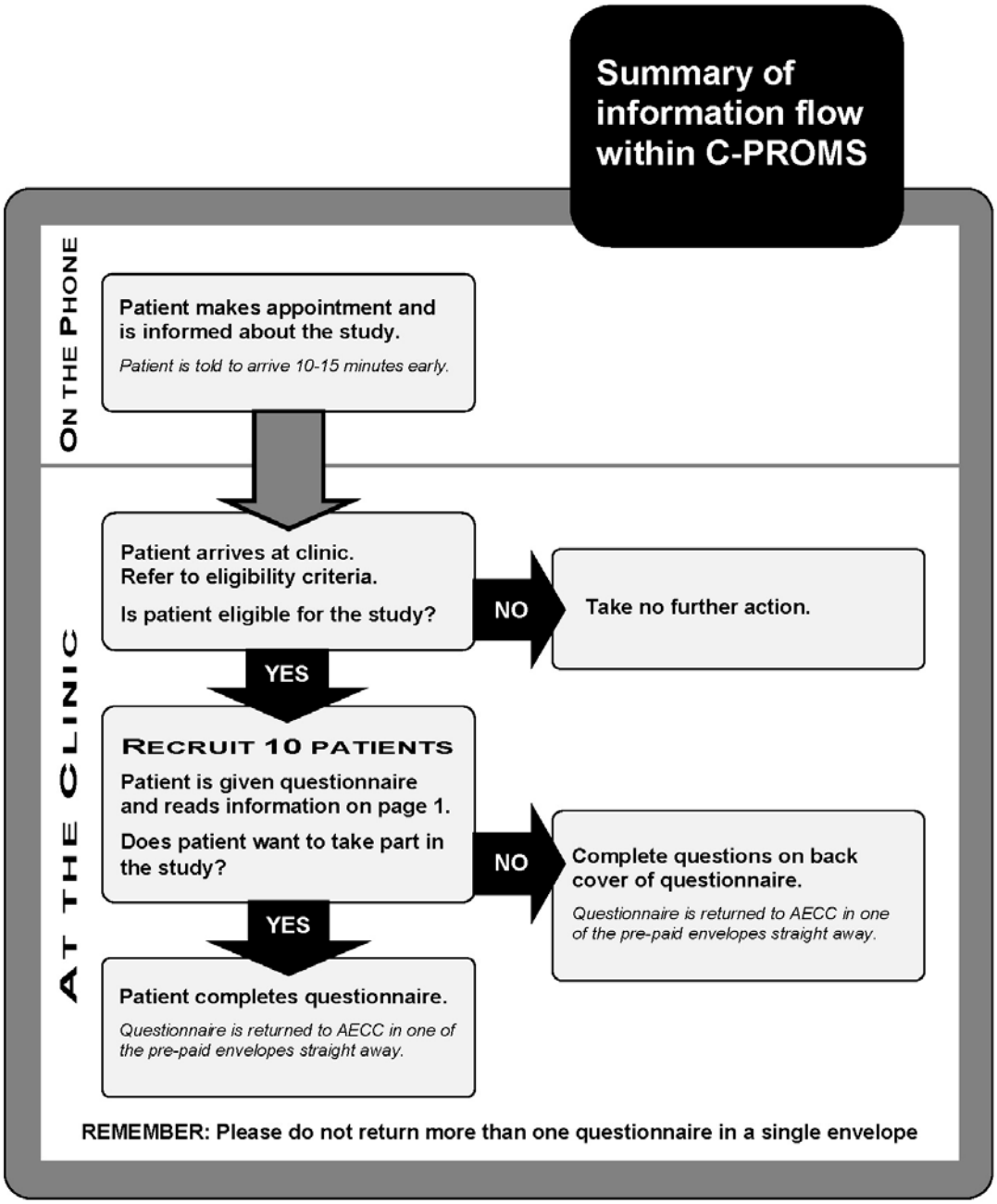

Figure 6.1: Data collection process in pilot clinics.

Approximately five working days prior to the follow-up data collection point at three months, patients receiving care were mailed the follow-up questionnaire along with a cover letter and a pre-paid envelope. Participants were given the option to complete the questionnaire online by following a web link provided on the cover page of the paper questionnaire. Non-responders were sent a first reminder via phone and a second reminder via text message and/or electronic mail two and four weeks after the second data collection point respectively. A final reminder was conducted via telephone five weeks after the follow-up data collection point. Following completion of reminder procedures, participating chiropractors and/or clinic staff were sent the number of patient visits form requesting the number of visits participants made to the clinic between baseline and follow-up data collection points.

6.3.3 Procedures of data analysis

Analysis of written notes

A qualitative approach based on thematic analysis[241, 242] was used taking into consideration the verbal comments received from the pilot practitioners and the reflective notes taken as the study proceeded. Through systematic analysis of the written notes, main themes emerged.

Analysis of patient data

Baseline demographics were reported using descriptive statistics. Data from the baseline and follow-up questionnaires were scrutinised and the frequency of irregularities or inconsistencies in these recorded. Based on these recordings, those questionnaire items which required action were identified.

6.4 Results

Since it was difficult to contact practitioners on the telephone, the majority of feedback was received via electronic mail. Thirty-eight questionnaires were received from the pilot clinics, with only one of the practitioners failing to collect data on ten consecutive patients. This appeared to be largely due to the fact that this practitioner had recently started practising on his own and thus was seeing a limited number of new patients. Thirty-two patients consented to participate in the study, with 17 being male. The mean age of these patients was 43 (SD = 15.9) years. Twenty-one of the

patients consenting to participate responded to the follow-up questionnaire and two of these patients submitted their response online. Analysis of the written notes and patient data revealed two main themes: 1) issues pertaining to the data collection process and resulting changes, and 2) issues pertaining to the clarity of the documentation and resulting changes.

6.4.1 Issues pertaining to the data collection process and resulting changes

The results are presented in Table 6.1. All practitioners reported that conducting the study did not significantly disrupt their normal practice patterns and, in most clinics, completion of the baseline questionnaire took less time than initially anticipated. A number of changes were made to improve patient recruitment including adapting the data collection process for multi-practitioner clinics, and modifying the procedures regarding participants non-amenable to care and those participants not consenting to participate in the study. The reminder process was also addressed. Since telephone reminders did not increase the number of patients responding at follow-up, these reminders were not conducted in the main study.

6.4.2 Issues pertaining to the clarity of the documentation and resulting changes

The results are presented in Table 6.2. No issues regarding clarity were identified by practitioners. Patient data revealed that asking about the duration between recovery of low back pain and completion of the follow-up questionnaire was confusing for patients and, thus, this item was amended in the follow-up questionnaire. In addition, a number of minor changes were made to the follow-up questionnaire and the accompanying cover letter, as well as to the number of visits form, so as to improve the understandability of these documents.

Table 6.1

Issues pertaining to the data collection process and resulting changes.

Issue (pilot study)		Change (main study)
Patient recruitment practitioner specific *The four participating chiropractors were working in multi-practitioner clinics. These practitioners commented that involving the clinic as whole as opposed to individual clinicians would maximise the number of new low back pain patients recruited in the study.*	➔	Patient recruitment made clinic specific *The instructions were modified in the user guide. Making the study clinic specific allowed for any new low back pain patients attending multi-practitioner clinics to be recruited in the study.*
Baseline questionnaire returned uncompleted for non-consenting participants *If patients did not consent to participate in the pilot study, the baseline questionnaire was returned uncompleted with patient's gender and birth date recorded by clinic staff on the back cover of this questionnaire. A substantial number (6) of baseline questionnaires were returned uncompleted for these patients.*	➔	No record was kept of non-consenting participants *The user guide and baseline questionnaire were modified. If patients did not consent to participate in the study, the baseline questionnaire was returned to clinic staff and no further action was taken.*
No record of patients non-amenable to care *One practitioner commented on this issue. Since there was no record of patients non-amenable to care, the follow-up questionnaire may have been posted to patients who did not receive care.*	➔	Information recorded at the back of the baseline questionnaire *The user guide and baseline questionnaire were modified. After the initial consultation (with or without treatment), clinic staff recorded on the back cover of the baseline questionnaire whether the patient was receiving / would receive care at the clinic.*
Baseline questionnaire completion time: 10-15 minutes *All but one practitioner reported that patients completed the baseline questionnaire on average between 5 to 10 minutes.*	➔	Baseline questionnaire completion time: 5-10 minutes *The instructions in the user guide were modified.*
Third reminder conducted over telephone for non-responders at follow-up *None of the participants responded to the telephone reminders.*	➔	No third reminder was conducted *Two reminders were conducted: first, via post, and, second, via electronic mail/text message.*

Table 6.2

Issues pertaining to the clarity of the documentation and resulting changes.

Issue (pilot study)		Change (main study)
Duration between recovery from low back pain and completion of the follow-up questionnaire *Patients were asked whether they were recovered (i.e. free of pain, able to carry out usual activities and achieved an acceptable quality of life for a whole month) at the time of completion of the questionnaire and, if so, for how long, over a whole month, they had been in this state. However, patient data revealed inconsistencies in the answers to this item:* *• In 3 cases, the patient was defined as 'recovered' in one or more dimension(s) (i.e. pain, usual activities and/or quality of life) but did not complete the duration box.* *• In 3 cases, the patient was defined as 'recovered' in one or more dimension(s) but a duration of less than four weeks was reported (i.e. not recovered).*	➔	Item removed from follow-up questionnaire *Patients were asked, using the same definitions, whether they were recovered anytime during the previous 3 months and whether they were still recovered at the time of completion of the questionnaire (i.e. 'today').*
Cover letter for the attention of participants *It may have been unclear that participants had to return the follow-up questionnaire even if they had completed their treatment. One participant stated during a reminder conducted over the telephone:* *• '... but I am not going to the chiropractor anymore so why would I have to complete the questionnaire?'*	➔	Cover letter amended *This matter was clearly explained in the cover letter accompanying the follow-up questionnaire.*
Follow-up questionnaire instructions *The additional time required by participants responding to reminders was not reflected in these instructions (reflective notes).*	➔	Follow-up questionnaire instructions amended *Follow-up questionnaire instructions were reworded so as to take into consideration this additional period of time.*
Number of treatments made to clinic *The difference between a treatment session and an initial consultation may be unclear to patients (reflective notes).*	➔	Number of visits made to clinic *'Number of treatments' reworded to 'number of visits' in the follow-up questionnaire and in the number of visits form.*
Overall satisfaction scale *This scale did not provide information about specific aspects of the delivery of care (reflective notes).*	➔	Satisfaction scale replaced with more detailed scale *This scale provided information about the time and explanations given by the chiropractor as well as the patient's involvement in decisions about care.*

6.5 Conclusion

This pilot study provided an opportunity to evaluate all aspects of data collection within the actual setting of a chiropractic practice, and as such was instrumental in facilitating and informing the main study. The data obtained in this pilot study led to changes to both the data collection process and documentation, of which the main changes included rewording the questions requesting information on recovery from low back pain, and improving the reminder and patient recruitment processes.

Due to the small sample size, it is unknown whether the patients and clinics included in this study provided sufficient heterogeneity to account for all the issues that could arise in the subsequent main study. However, as none of the participants in this pilot study, neither patients nor practitioners, were included in the main study, increasing the pilot sample size would have meant a reduction in available participants for the main study. A further limitation of this pilot study is that although comments were received from practitioners, the patients were not questioned regarding the clarity of the documentation. It may therefore have been useful to conduct face-to-face interviews with patients following the data collection process.

All data from the pilot study were received by June 2010, and following analysis and consequential revisions, the main study was implemented in August 2010.

CHAPTER 7

Main study

7.1 Introduction

The aims of the main study were to use the data collection instrument and procedures developed in the pilot study to assess the quality and costs of care in low back patients undergoing chiropractic treatment. In addition, observations were made to ensure the instrument was fit for purpose.

7.2 Methods

7.2.1 Study design

The study was designed as prospective single cohort multi-centre study in which low back pain patients receiving chiropractic treatment were followed over a period of three months from the date of their initial consultation.

7.2.2 Patient sample

Sampling method

Quality of care research resembles survey investigations closely in that findings in a portion of the population (i.e. sample) are generalized to the population under consideration (i.e. sampling frame),[243] which in the present case was new episode low back pain patients undergoing chiropractic treatment. In survey research, the population is normally too large or unknown and, therefore, a portion of the sampling frame is selected for inclusion in the research study using sampling methods.[244] Such methods aim to reduce bias in the selection of subjects, which may decrease the generalisability of results to the population under investigation.[245]

Probability sampling is often considered as the method of choice when obtaining a sample.[246] In probability sampling, potential participants are randomly or systematically selected from the sampling frame so as to ensure each patient has the same chance of being included in the study. [244, 245] This method was not possible in this study as it was not feasible to construct a sampling frame or, in other words, a list of all people in the United Kingdom planning to receive chiropractic treatment

for a new episode of low back pain. Moreover, low back pain patients should be treated immediately in accordance with clinical guidelines[239, 247] and thus these patients had to be recruited in the study without delay. In the present study, a particular form of non-probability sampling was used called consecutive sampling. In consecutive sampling, a convenience (i.e. easy to access) sample of patients or subjects is selected in a consecutive manner.[246] Consecutive sampling is considered to be the most appropriate non-probability sampling method since this procedure reduces the chance of participants being selected arbitrarily by practitioners or clinic staff.[245] Chiropractic clinics were asked to recruit 10 patients into the study which was considered a feasible sample in that this number would not be overly onerous to the clinic.

Sample size

In order to determine the number of participants that should be included in a study, some form of effect size, such as the magnitude of the difference or effect between patient groups, is typically required. No effect size as such was measured to evaluate the quality and related cost of care in this study and, therefore, traditional sample size statistics based on effect size and statistical power were not relevant.[248] Survey sample size statistics may appear to be more relevant in this situation but these procedures are based on the assumption that the entire population under consideration is known (i.e. sampling frame).[243] Without prior knowledge of the size of the sampling frame, the best alternative was to take as large a sample as possible within the resource constraints of the study. Incorrect inferences from the data collected are less likely to be made when samples are larger rather than small. Furthermore, the larger the sample studied, the more likely the sample findings will be representative of the sampling frame and population.[249]

Although, sample size estimation could not be performed for meeting most of the study objectives, it was necessary to perform this calculation for one of the research questions. This was to determine the number of patient files to be screened for the evaluation of patients' accuracy of recall of number of visits. The accuracy of recall was determined by measuring the difference between the mean number of visits made to the clinic as reported by patients and the mean of the same information reported in patient files. The effect size corresponds to the magnitude of the

difference between two means and, thus, an estimation of sample size could be performed.[250] Sample size is calculated taking into account a number of factors. First, the alpha level (α) or level of statistical significance which guards against the null-hypothesis being incorrectly rejected (i.e. type I error), second, the beta level (β) which guards against the null-hypothesis being incorrectly accepted (i.e. type II error) and, third, the statistical power (P), which is defined as P = 1-β.[248, 249] The alpha level and statistical power are conventionally set at 0.05 or 5% and 0.80 or 80% respectively.[248] Using the software GPower 3.1, a moderate effect size (0.30)[251] yielded a sample size of 84 subjects. As a result, patient files were screened in 17 clinics assuming a conservative patient response rate at follow-up of 50% (i.e. five files per clinic), which gave a total of 85 subjects.

7.2.3 Recruitment and sample of chiropractors

The study was promoted to chiropractors listed as members of the British Chiropractic Association from the beginning of the study (February 2009) to the start of data collection (August 2010). Practitioners were invited to participate in the study through presentations held at conferences and articles published in periodicals as well as emails sent to them via relevant associations. As an inducement to participate in the study, each participating practitioner/clinic manager was entered in a prize draw, which was conducted at the end of data collection. The companies and institutions that donated these items did not place any conditions on these contributions in terms of research design, conduct and publication.

The main study was conducted in clinics between August 2010 and July 2011. Those clinics that responded to the invitation to participate were mailed a study pack containing a cover letter, a user guide, 10 baseline questionnaires (Appendix 2) and 10 pre-paid envelopes. The participating clinics were allocated to three groups that were mailed the study pack on different dates so that not all clinics were recruited at the same time.

Two weeks following dispatch of their study pack, participating chiropractors and/or clinic staff were contacted to confirm receipt of the documentation and to determine whether they had any queries regarding the data collection process.

7.2.4 Data collection procedures

Chiropractors and/or their staff were asked to recruit 10 consecutive new low back patients who fulfilled the inclusion criteria. A diagram of the data collection process, revised following the pilot study, is presented in Figure 7.1. Eligible patients were asked to arrive at the clinic 5 to 10 minutes before their initial consultation to allow sufficient time to inform themselves about the study and complete the baseline questionnaire. After reading the information at the start of the questionnaire, patients decided whether or not they wished to participate in the study. If patients decided to take part, they were asked to sign the informed consent section of the questionnaire and then respond to questions. Following the initial consultation (with or without treatment), the chiropractor or clinic staff recorded at the end of the questionnaire whether the patient was receiving/would receive chiropractic care, and returned the document in a single pre-paid envelope. If patients decided that they did not want to take part in the study, they were asked to return the questionnaire to clinic staff and no further action was taken.

Approximately five working days prior to the second data collection point at three months, participants were mailed the follow-up questionnaire (Appendix 2) along with a cover letter and a pre-paid envelope. If participants found it more convenient to submit the questionnaire online, they could do so by following a web link provided on the cover page of the paper questionnaire. Non-responders were sent a first reminder via phone and a second reminder via text message and/or electronic mail, two and four weeks after the second data collection point respectively. Following completion of reminder procedures, 17 clinics were randomly selected from the participating clinics database using computer generated numbers, and these clinics were sent the number of patient visits form requesting the number of visits participants made to the clinic between baseline and follow-up data collection points (Appendix 2).

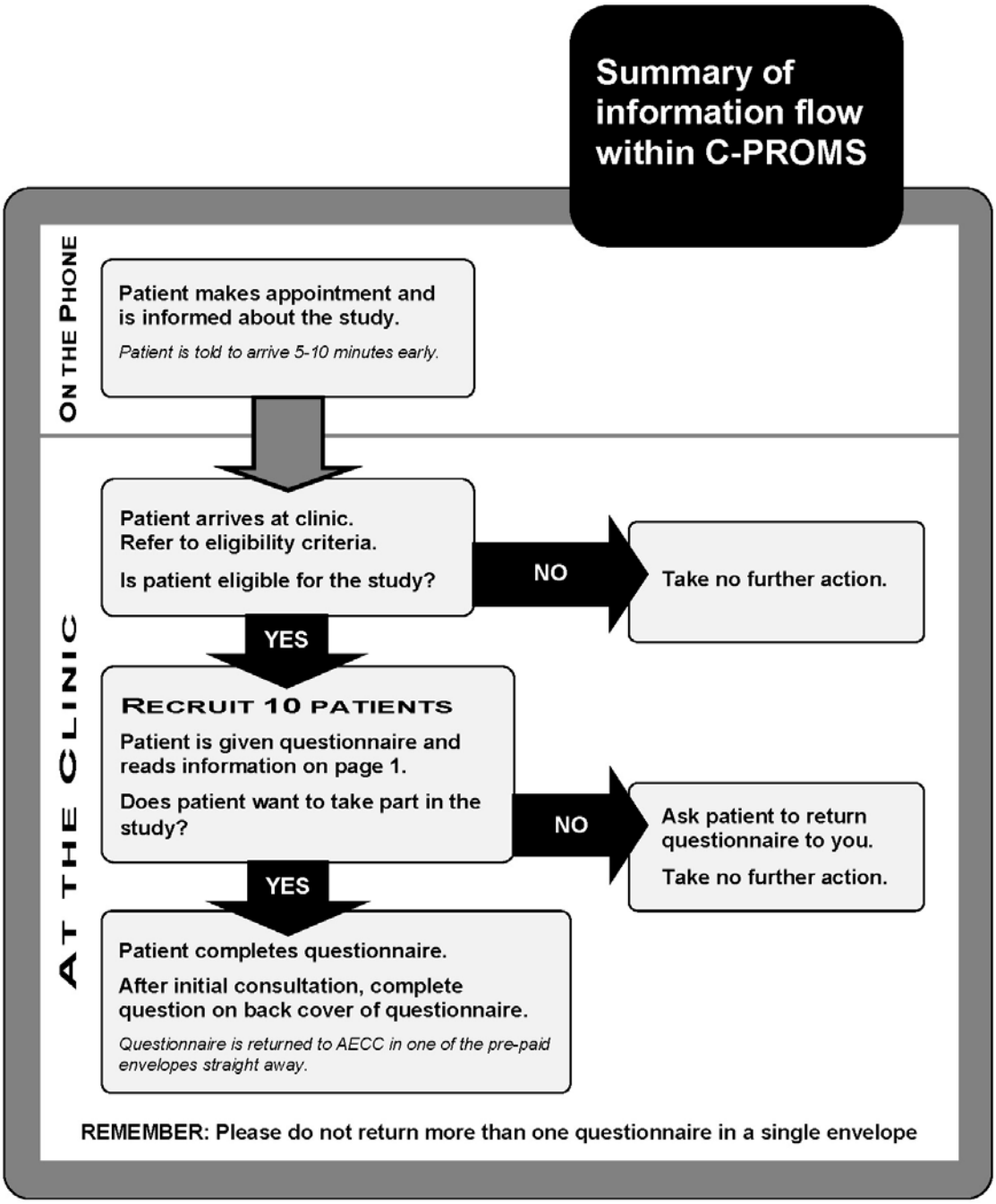

Figure 7.1: Data collection process in pilot clinics.

7.2.5 The chiropractic intervention

No restrictions or guidelines were given to chiropractors with regards to treatment and patients were managed as they normally would be in routine care. A number of therapeutic procedures are typically used by chiropractors in the United Kingdom including manipulation or adjustment, advice about therapeutic exercise and activities of daily living (e.g. postural and ergonomic advice), as well as psychosocial counseling.[252, 253] Although guidelines have been published recommending manual therapy (i.e. manipulative therapy, acupuncture and exercise) for the treatment of non-specific low back pain,[239, 247] there is currently no firm evidence that favours one treatment approach over another. Hence, this study was entirely pragmatic in terms of the nature of the intervention and the number of treatment sessions for each patient.

7.2.6 Ethics

After having been informed about the study, all patients wishing to participate were required to give written consent as part of the baseline questionnaire. Participants were informed that they could withdraw from the study at any time without prejudice and that the information they provided would remain anonymous. The study was granted approval by the AECC Research Ethics Sub-Committee in October 2009 (Appendix 3).

7.2.7 Quality check for data entry errors

Data were cleaned and investigated for data entry errors. A random selection, determined using computer generated numbers, of 177 questionnaires (approximately 25% of all questionnaires) was checked manually, in which no data entry errors were found. However, it was discovered, in a small number of patients, that data from aspects of the construct-specific recovery from low back pain questions had been entered in wrong columns, thus theses incorrect values were corrected.

7.2.8 Data analysis

Statistical analysis for this study was undertaken using SPSS version 20.0 (IBM, Inc., New York, USA). Histograms of the frequency distribution of the continuous variables are presented in Appendix 4A, 4B and 4C. These variables were

approximately normally distributed except for cost data in which the distribution was highly skewed.

Missing data were reported for all analyses, and as these data were less than 5% for all variables except lifestyle changes (ranging from 5% to 11%) and EQ-5D change scores (7%), a complete case analysis was performed. The use of this approach is substantiated by the work of Scheffer,[254] in which simulations using differing levels of missing data showed that a percentage of missing data less than 5% had no significant impact on the calculation of means and standard deviations irrespective of the pattern of missingness (i.e. missing or not missing at random).

In addition to descriptive analyses using mean and standard deviation for continuous variables as well as number and percent for categorical and ordinal variables, more detailed analyses were performed in order to answer the research questions of the study.

Documentation of health outcomes, patient experiences and costs of care as well as evaluation of outcome reporting methods

The scales of the RMDQ, BQ, EQ-5D and bothersomeness scale were transformed to cover an interval ranging from 0-100, thus enabling comparison between measures in spite of their different scoring intervals. Baseline and follow-up health status scores were compared using dependent t-tests. The raw change score for each health status measure was obtained by subtracting the follow-up score from the baseline score except for the EQ-5D for which the baseline score was subtracted from the follow-up score. The percentage change score was also determined for the individual BQ scales and the formula for this calculation was: (raw change score/baseline score)*100.[129]

The EQ-5D scores at baseline and follow-up were transformed into utilities using a representative British sample.[255] In addition, quality adjusted life years (QALYs) participants had experienced over the 3-month study period were estimated by calculating areas under the health utility curves,[163] with straight-line interpolation between utilities at baseline and follow-up (an example of this calculation is given in Appendix 5).

The raw and percentage minimal clinically important difference (MCIDr and MCID% respectively), which represent the cut-off of clinical improvement, were determined using three distribution-based methods, i.e. 0.5 ES,[159] 1 SEM,[145] and 1.96 RCI,[105] as well as one anchor-based method, i.e. ROC.[256] These four methods were selected as they have been the most frequently used and recommended in the field of outcomes research for low back pain.[107, 109, 146] The formulas used for the distribution-based methods were: half a standard deviation at baseline for the 0.5 ES method, the standard deviation at baseline multiplied by $\sqrt{(1 - \text{reliability coefficient})}$ for the 1 SEM method, and 1.96 multiplied by $\sqrt{(2SEM^2)}$ for the 1.96 RCI method.

In the ROC method, the GPE scale was used as the external criterion to determine the ability of the measure to diagnose patients correctly as clinically improved (i.e. sensitivity) and the ability to diagnose patients correctly as clinically non-improved (i.e. specificity). The participants who selected categories 'very much improved' or 'completely recoverd' on the GPE scale were considered clinically improved, and the change score on the outcome measure that maximised sensitivity and specificy indicated the MCID.

Using indirect methods of measuring improvement (i.e. using the cut-offs on RMDQ, BQ, EQ-5D and bothersomness scale), patients were classified as clinically improved or clinically non-improved and the proportion of patients clinically improved was determined. Confidence intervals for these proportions were obtained using the Unmodified Wald method described by Newcombe.[257] This procedure was also used to calculate confidence intervals for the percentage of patients rating the process of care as 'very helpful' or 'very good'.

To determine the diagnostic accuracy of each cut-off method, the sensitivity, specificity and Cohen's Kappa coefficient were determined for each threshold approach. Sensitivity and specificity were calculated using 2x2 tables (an example of this calculation is given in Appendix 6), and ROC plots were constructed to explore the sensitivity and 1-specficity of each cut-off approach using an external criterion of improvement. The criterion used in this study was the proportion of patients clinically improved using the direct method of measuring improvement (i.e. patients categorized as clinically improved on the GPE scale).

Cohen's Kappa coefficient (i.e. non-weighted Kappa) was used as an indicator of overall agreement between both methods of determining improvement and represents percentage agreement between methods corrected for chance.[258] The values of Kappa can range from -1 to +1 (i.e. perfect agreement), although, in practice, values below 0 (i.e. agreement no better than chance) rarely occur. The Kappa coefficient was evaluated using the categorisation by Fleiss: ≥ 0.75, strong agreement; 0.4–0.75, moderate agreement; and ≤ 0.4, poor agreement.[259]

Costs of care were calculated by multiplying unit costs by health care usage. Unit costs were determined from relevant national databases and values were adjusted for inflation when required (Appendix 7). Ninety-five percent confidence intervals for mean costs were calculated using bias-corrected and accelerated non-parametric bootstrapping with 1000 replications.[179]

To examine for potential biases from loss to follow-up, socio-demographic and clinical characteristics, as well as baseline health status scores, for participants who completed and did not complete the follow-up questionnaire were compared using the independent t-test for continuous variables and the Chi^2 test for categorical variables.

Evaluation of data collection instrument

Evaluation of the responsiveness of health status measures included the assessment of both internal and external responsiveness. Internal responsiveness reflects the ability of a measure to change over a pre-specified period, and external responsiveness denotes the extent to which change in a measure over a pre-specified period relates to corresponding change in a reference criterion.[260] Internal responsiveness is typically determined using one of two methods: i) Cohen's effect size (i.e. change in the measure divided by the standard deviation of baseline scores) and the standardized response mean (i.e. change in the measure divided by the standard deviation of change scores).[261]

In the present study, Cohen's effect size was selected as it has been the most frequently used to assess internal responsiveness in low back pain research and has been recommended by experts in this field.[29, 261] Indeed, Norman and colleagues recommend the use of this measure as anchoring observed change against variability

at baseline may be less vulnerable to extreme values than its alternative. In addition, Cohen's effect size facilitates interpretation since effect sizes can be compared to standards of size such as Cohen's small (0.2), medium (0.5) and large (0.8) thresholds.[137]

Internal responsiveness methods share the limitation that they do not relate change in the measure to an external measure of clinical change (i.e. external responsiveness), thus the clinical importance of the observed change cannot be determined.[260] To remedy this problem some investigators have calculated an effect size statistic only for patients who rate their health as clinically improved.[261] The major weakness of this approach is that it does not involve a comparison of change in the measure between patients who are clinically improved and clinically non-improved.[260]

In the present study, external responsiveness of the health status measures was determined using the area under the curve (AUC) of ROC analysis.[262] The ROC curves were plotted as sensitivity against 1-specificity for different cut-off points in change scores. The area under the curve is an indicator of the probability of correctly identifying the clinically improved patients from the non-clinically improved patients. An AUC of 0.5 indicates chance discrimination, whereas a minimal value of at least 0.7, arbitrarily, is considered to be acceptable and 1.0 perfect discrimination.

The criterion validity (accuracy) of patient-reported number of visits made to the clinic was assessed using the non-parametric approach to comparing methods by Bland and Altman,[263] which involved plotting the differences between patient-reported visits and visits as based on patient files (patient-report – patient file) versus mean values of the two methods. The number of visits obtained using both methods were compared using Wilcoxon signed-rank test, and the significance of the relationship between the differences versus the mean was assessed using Spearman correlation coefficient. In addition, the limits within which the majority of differences fell were determined using visual inspection of the graph (accurate reporters were considered as those values between -1 and +1).

Evaluation of the construct validity of measuring complete recovery from low back pain using construct-specific questions was investigated by assessing the agreement between patients categorised as completely recovered using the GPE scale and the

construct-specific questions (i.e. acceptable quality of life, no disability and no pain for a whole month). Cohen's Kappa coefficient (i.e. non-weighted Kappa) was used as an indicator of overall agreement. In addition, positive percent agreement (PPA) and negative percent agreement (NPA) were calculated to provide information about the types and sources of potential disagreement.[264] Positive percent agreement depicts the percentage of patients correctly categorised as completely recovered (i.e. as per GPE scale) using the construct-specific method, and NPA indicates the percentage of patients correctly categorised as not completely recovered using the same method. The calculation of PPA and NPA is analogous to that of sensitivity and specificity (outlined in Appendix 6) respectively, with the only difference being that an imperfect reference standard is used for the determination of PPA and NPA.

7.3 Results

7.3.1 Response rate

Seventy-one clinics agreed to participate in the study, with a total of 123 chiropractors working in these practices. Of these clinics, three single-practitioner clinics resigned from the study after receiving the data collection pack. The reasons given for this were: i) the study was too complex; ii) the receptionists did not feel comfortable conducting the study; and iii) the practitioner left the clinic for unforeseen circumstances.

Given that clinics were each asked to return 10 patient-reported baseline questionnaires, the maximum possible number of participants for the remaining clinics was 680. These clinics returned complete sets of baseline data from 428 patients. The main reason for not returning all 10 baseline questionnaires was a lack of new patients fulfilling the inclusion criteria within a reasonable time span for the study.

A diagram of the flow of data throughout the study is shown in Figure 7.2. From the 428 returned baseline questionnaires, seven forms were discarded due to non-compliance with the inclusion criteria or excessive missing data, thus 421 patients formed the baseline sample of the study. The number of patients who completed the follow-up questionnaire was 238 (57% of the baseline sample), and of these, 214 (90%) returned the questionnaire by post and 24 (10%) submitted the questionnaire online.

Baseline data of the responder and non-responder cohorts (i.e. patients who completed the baseline questionnaire and did not complete the follow-up questionnaire) are shown in Table 7.1. Significant differences ($p < 0.05$) between responders and non-responders were found for age and gender. The patients who responded were older (mean = 47.3 years, SD = 13.13 years) than non-responders (mean = 40.4 years, SD = 14.45 years), and women were more likely to respond than men, with 136 (56%) of the responders being female. No significant differences between responders and non-responders were found for all other clinical and socio-demographic variables (i.e. work status, pain history and medication usage) and for all baseline health status scores.

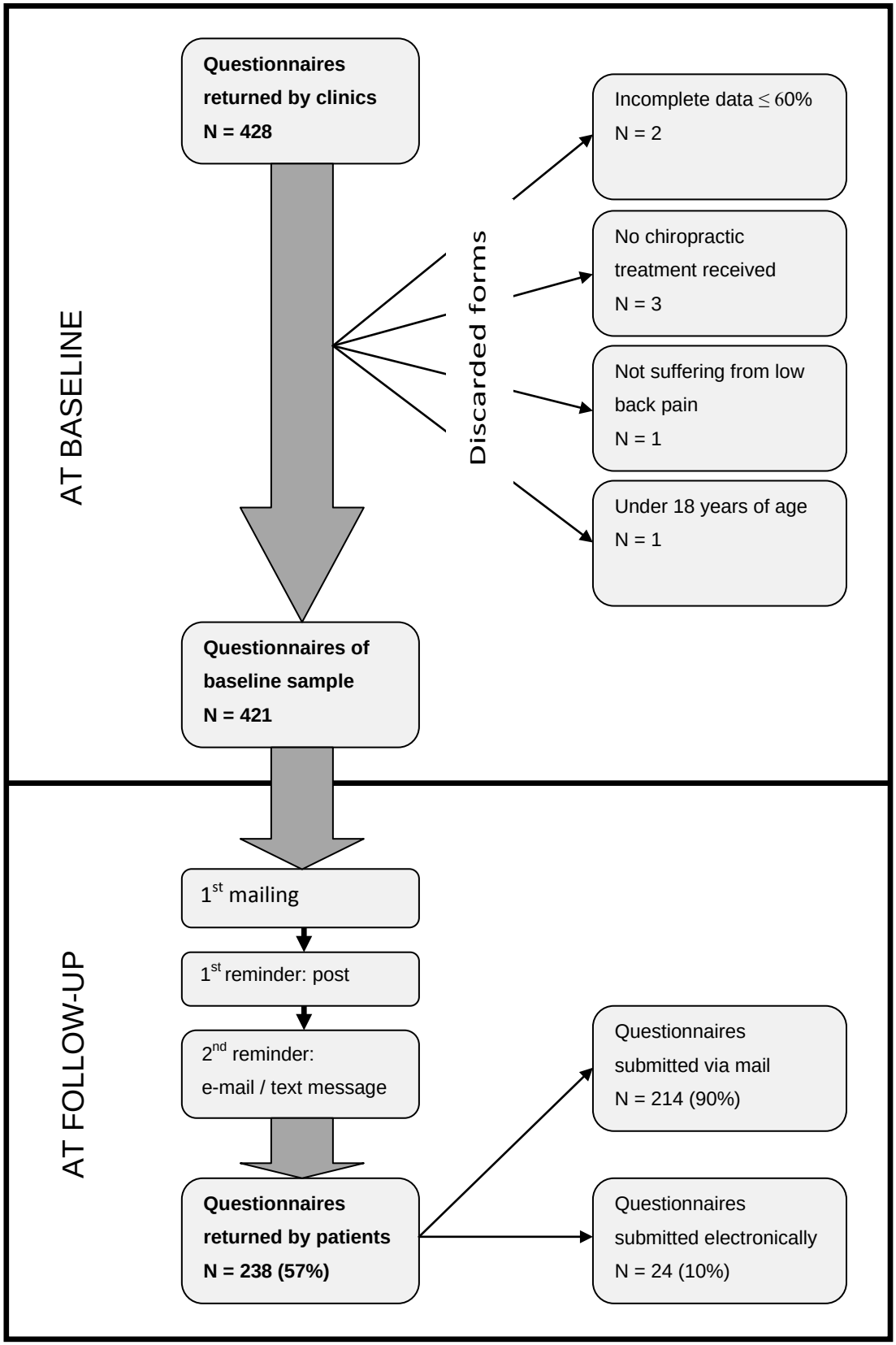

Figure 7.2: Diagram of flow of data throughout the study.

Table 7.1: Comparative analysis between responders and non-responders. Significant variables are marked with an asterisk (*).

Variable		**Responders (n = 238)**	**Non-responders (n = 183)**
*Age	Mean (SD, range) number of years	47.3 (14.45, 19-88)	40.4 (13.13, 18-78)
	Missing	2	2
*Gender	Male	104 (44)	102 (56)
	Female	134 (56)	81 (44)
	Missing	0	0
Work status	In paid (including self) employment	183 (77)	152 (83)
	At home and not looking for work	8 (3)	6 (3)
	Unemployed because of back pain	1 (< 1)	2 (1)
	Unemployed because of other reasons	7 (3)	5 (3)
	Retired	35 (15)	14 (8)
	Student	4 (2)	4 (2)
	Missing	0	0
Pain history	< 3 months	84 (35)	76 (42)
	3-6 months	37 (16)	18 (10)
	7-12 months	29 (12)	21 (12)
	1-2 years	29 (12)	19 (10)
	3-5 years	23 (10)	15 (8)
	6-10 years	14 (6)	14 (8)
	> 10 years	21 (9)	19 (10)
	Missing	1 (< 1)	1 (< 1)
Medication usage	Never	50 (21)	33 (18)
	Rarely	53 (22)	32 (18)
	Sometimes	83 (35)	76 (42)
	Every day	52 (22)	40 (22)
	Missing	0	2 (< 1)

Values are frequency (%) unless stated otherwise. N = number of observations. Statistical significance ($p < 0.05$) determined using Chi^2 test for categorical and independent t-test for continuous variables.

Table 7.1 *(continued)*: Comparative analysis between responders and non-responders. Significant variables are marked with an asterisk (*).

Variable		**Responders (n = 238)**	**Non-responders (n = 183)**
RMDQ	Mean (SD) score	7.4 (5.13)	8.0 (5.46)
	Missing	0	0
BQ	Mean (SD) score	29.4 (15.41)	30.8 (14.62)
	Missing	5	2
EQ-5D	Mean (SD) score	0.59 (0.27)	0.60 (0.25)
	Missing	10	6
Bothersomeness scale	Mean (SD) score	3.5 (0.96)	3.5 (0.95)
	Missing	0	0

RMDQ = Roland-Morris Disability Questionnaire. BQ = Bournemouth Questionnaire.
EQ-5D = EuroQol-5D.

7.3.2 Sample characteristics

The socio-demographic and clinical characteristics of the baseline sample are presented in Table 7.2. Of the 421 patients, gender was equally distributed (206 male participants or 49% of sample) and the mean age was 44.3 years (SD = 14.30, range = 18-88) years. The majority of patients were in paid employment (335, 80%) and only a small proportion of participants (3, 1%) were unemployed because of back pain. The remaining patients were either not looking for work, unemployed for reasons other than back pain, retired or studying. The chronicity of low back pain ranged from less than 3 months to more than 10 years, with 169 (38%) participants suffering from an acute/subacute low back pain episode for less than 3 months. The majority of patients (251, 60%) were using pain medication for their back pain either ‘sometimes’ or ‘everyday’, while the remaining participants used these drugs either ‘rarely’ or ‘never’.

Table 7.2: Baseline description of 421 patients.

Variable		
Age	Mean (SD, range) years	44.3 (14.30, 18-88)
	Missing	4 (1)
Gender	Male	206 (49)
	Female	215 (51)
	Missing	0
Work status	In paid (including self) employment	335 (80)
	At home and not looking for work	14 (3)
	Unemployed because of back pain	3 (1)
	Unemployed because of other reasons	12 (3)
	Retired	49 (12)
	Student	8 (2)
	Missing	0
Pain history	< 3 months	169 (38)
	3-6 months	55 (13)
	7-12 months	50 (12)
	1-2 years	48 (12)
	3-5 years	38 (9)
	6-10 years	28 (7)
	> 10 years	40 (10)
	Missing	2 (< 1)
Medication usage	Never	83 (20)
	Rarely	85 (20)
	Sometimes	159 (38)
	Every day	92 (22)
	Missing	2 (< 1)

Values are number (%) unless stated otherwise.

7.3.3 Health outcomes

Health status scores are presented in Table 7.3. All health status measures including the RMDQ, the total BQ and BQ subscales, the EQ-5D and the bothersomeness scale showed significant raw change scores ($p < 0.001$) between baseline and follow-up data collection points, and using the calculation given in Appendix 5, the mean QALYs over the 3-month period was 0.174 (95% CI = 0.168 to 0.180).

Despite raw change scores being statistically significant, there were important differences between measures with regards to percentage change scores. The percentage change scores for the RMDQ and total BQ were similar (62%) whereas these values were lower for the EQ-5D and bothersomeness scale (34% and 38% respectively).

The mean RMDQ and total BQ scores were, respectively, moderate at baseline (mean = 30.8, SD = 21.37; mean = 38.1, SD = 19.99) and low at follow-up (mean = 11.6, SD = 16.21; mean = 14.6, SD = 15.33). However, the mean bothersomeness score was high at baseline (mean = 69.2, SD = 19.26) and moderate at follow-up (mean = 42.8, SD = 18.62), and the mean EQ-5D utility score (i.e. higher utility score indicates better health) was moderate at baseline (mean = 59.5, SD = 27.14) and high at follow-up (mean = 79.8, SD = 20.22).

The scores of the individual BQ domains generally tended towards the centre of the scales at baseline and towards the low end of the scales at follow-up. The percentage change scores of the BQ subscales ranged from 57% to 68%. At baseline, pain levels were moderate to severe (mean = 57.7, SD = 24.56), depression levels were low (mean = 26.9, SD =28.76), and all other BQ domains were moderately affected (mean scores ranging from 36.8, SD = 29.15, to 45.3, SD = 27.34). At the 3-month follow-up, the mean scores on the BQ subscales ranged from 10.4 (SD = 18.44) to 24.3 (SD = 22.70).

Table 7.3: Health status scores (0-100 scale) in 238 participants of Roland-Morris Disability Questionnaire (RMDQ), Bournemouth Questionnaire (BQ), EuroQol-5D (EQ-5D) and bothersomeness scale (BS).

	Baseline	**Follow-up**	**Missing**	***Raw change (95% CI)**	**Percentage change (%)**
RMDQ	30.8 (21.37)	11.6 (16.21)	0	19.2 (16.31 to 22.00)	62
BQ					
Pain	57.7 (24.56)	24.3 (22.70)	3	33.5 (29.73 to 37.25)	58
Disability in activities of daily living	45.3 (27.34)	16.5 (20.75)	2	28.8 (24.85 to 32.78)	64
Disability in social activities	40.4 (31.20)	12.9 (20.15)	4	27.5 (23.15 to 31.89)	68
Anxiety	36.8 (29.15)	13.9 (20.48)	1	22.9 (19.06 to 26.68)	62
Depression	26.9 (28.76)	10.4 (18.44)	2	16.5 (12.84 to 20.21)	61
Fear avoidance beliefs	44.4 (30.30)	19.1 (24.31)	1	25.3 (20.97 to 29.58)	57
Locus of control	42.0 (27.11)	17.9 (21.23)	3	24.1 (19.79 to 28.38)	57
Total	38.1 (19.99)	14.6 (15.33)	8	23.5 (20.62 to 26.47)	62
EQ-5D (utility)	59.5 (27.14)	79.8 (20.22)	18	20.3 (16.43 to 24.23)	34
BS	69.2 (19.26)	42.8 (18.62)	1	26.5 (23.32 to 29.66)	38

Values are in mean (SD) unless stated otherwise. Ranges of original scales: RMDQ = 0-24; total BQ = 0-77; Individual BQ scales = 0-10; EQ-5D = 0-1; BS = 1-5. * Significant difference ($p < 0.001$) between baseline and follow-up score using dependent t-test.

On the GPE scale (values given in Figure 7.3), of the 238 patients at follow-up, 45 (19%, 95% CI = 14.0% to 23.9%) were categorised as 'completely recovered' and 168 (71%, 95% CI = 64.8% to 76.3%) were considered clinically improved (i.e. category 'very much improved' and 'completely recovered'). Construct-specific recovery from low back is shown in Table 7.4. Eighty-one (34%) of the patients at follow-up were pain free for a whole month at any time during the study, and 66 (81%) of these patients were still in this pain-free period at follow-up. One hundred and thirty-seven (58%) and 170 (71%) of the patients at follow-up were able to carry out usual activities and achieved an acceptable quality of life, respectively, without interference from back pain for a whole month at any time during the study, and 115 (84%) and 154 (91%) of these patients respectively were still in these interference-free periods at follow-up. Complete recovery from low back pain, determined by recovery on all three dimensions (i.e. acceptable quality of life, no disability and no pain), at any time during the study, was achieved by 73 (31%) of the patients at follow-up, and 61 (84%) of these patients were still completely recovered at follow-up. This indicates that 12 (5%) of the patients at follow-up had a recurrence of their presenting episode of low back pain within the 3-month period of the study.

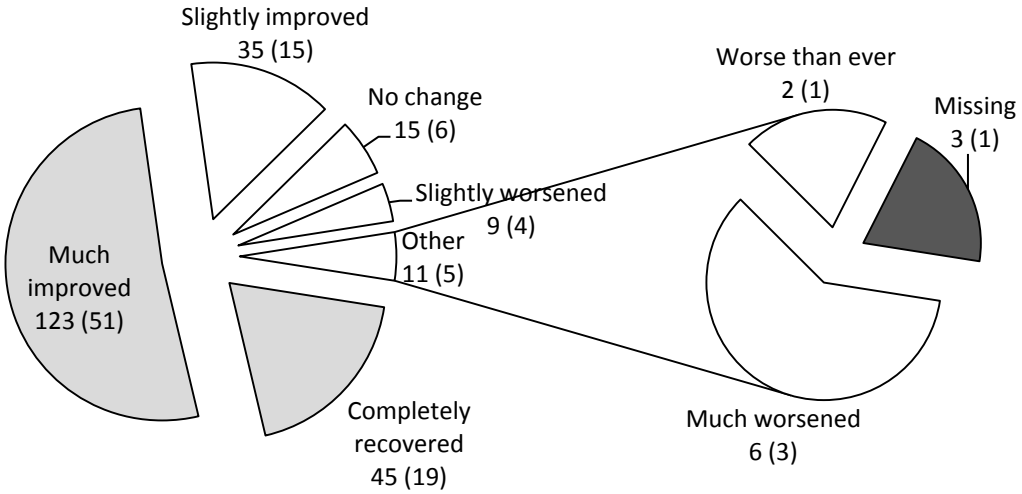

Figure 7.3: Frequency (%) perceived level of improvement in 238 participants, i.e. global perceived effect scale.

Table 7.4: Construct-specific recovery from low back pain in 238 participants.

At anytime during the study i.e. since completing the baseline questionnaire				**At follow-up** i.e. on the day of completion of the follow-up questionnaire		
Free of back pain for a whole month	Yes	81 (34)	If yes →	Still in pain-free period	Yes	66 (81)
	No	156 (66)			No	15 (19)
	Missing	1 (< 1)			Missing	0
Able to carry out usual activities without interference from back pain for a whole month	Yes	137 (58)	If yes →	Still in interference-free period	Yes	115 (84)
	No	100 (42)			No	21 (15)
	Missing	1 (< 1)			Missing	1 (< 1)
Achieved an acceptable quality of life without interference from back pain for a whole month	Yes	170 (71)	If yes →	Still in interference-free period	Yes	154 (91)
	No	67 (28)			No	15 (9)
	Missing	1 (< 1)			Missing	1 (< 1)
Complete recovery i.e. ‘yes’ to the three previous questions about pain, usual activities and quality of life	Yes	73 (31)	If yes →	Still completely recovered	Yes	61 (84)
	No	164 (69)			No	12 (16)
	Missing	1 (< 1)			Missing	0

Values are frequency (%).

The MCIDr and MCID% values (i.e. cut-offs) for each health status measure are presented in Figure 7.4. Sensitivity and specificity values for a range of cut-off points for each measure using ROC analysis can be found in Appendix 8. There was large variability in both the MCIDr and MCID% values within the instruments and across measures, calculated by the distribution-based methods (i.e. 1.96 RCI, 0.5 ES and 1 SEM) and anchor-based method (i.e. ROC). In general, however, a similar pattern of results was obtained for the MCID% values for all measures except the EQ-5D. The MCID% values of the RMDQ, BQ and bothersomeness scale determined using the 1 SEM, 0.5 ES, 1.96 RCI, and ROC respectively showed the same increasing order: 15%, 35%, 43% and 61% for the RMDQ; 12%, 26%, 32% and 36% for the BQ; and 6%, 14%, 17% and 43% for the bothersomeness scale. The EQ-5D demonstrated a different pattern from its counterparts, with 1.96 RCI yielding the highest percentage MCID% (29%), 1 SEM yielding the lowest MCID% (10%) and 0.5 ES and ROC each yielding a similar MCID% (24%).

The proportions of patients improved for each measure, calculated by the indirect method of determining improvement (i.e. using the ROC, 1.96 RCI, 0.5 ES and 1 SEM cut-offs) are shown in Figure 7.5. There was large variation in the proportion of patients improved by the same method across measures and across different methods within measures. Generally, however, the proportions of patients clinically improved showed an inverse relationship compared to the corresponding MCID% cut-off values (i.e. the lower the MCID%, the higher the proportion of patients improved and vice-versa) for all measures except for the bothersomeness scale. These proportions, using the ROC, 1.96 RCI, 0.5 ES and 1 SEM cut-offs, respectively, were: 42%, 49%, 57% and 65% for the RMDQ; and 61%, 65%, 70% and 78% for the BQ. With respect to the EQ-5D, the proportion of patients clinically improved was highest using the 1 SEM cut-off (56%), lowest using the 1.96 RCI cut-off (42%), and similar using the 0.5 ES and ROC cut-offs (43%). Although different methods of determining the MCID yielded differing cut-offs for the bothersomeness scale, the proportion of patients clinically improved was similar using the 0.5 ES, 1 SEM and 1.96 RCI cut-offs (74%), and was nearly half this value (40%) using the ROC cut-off.

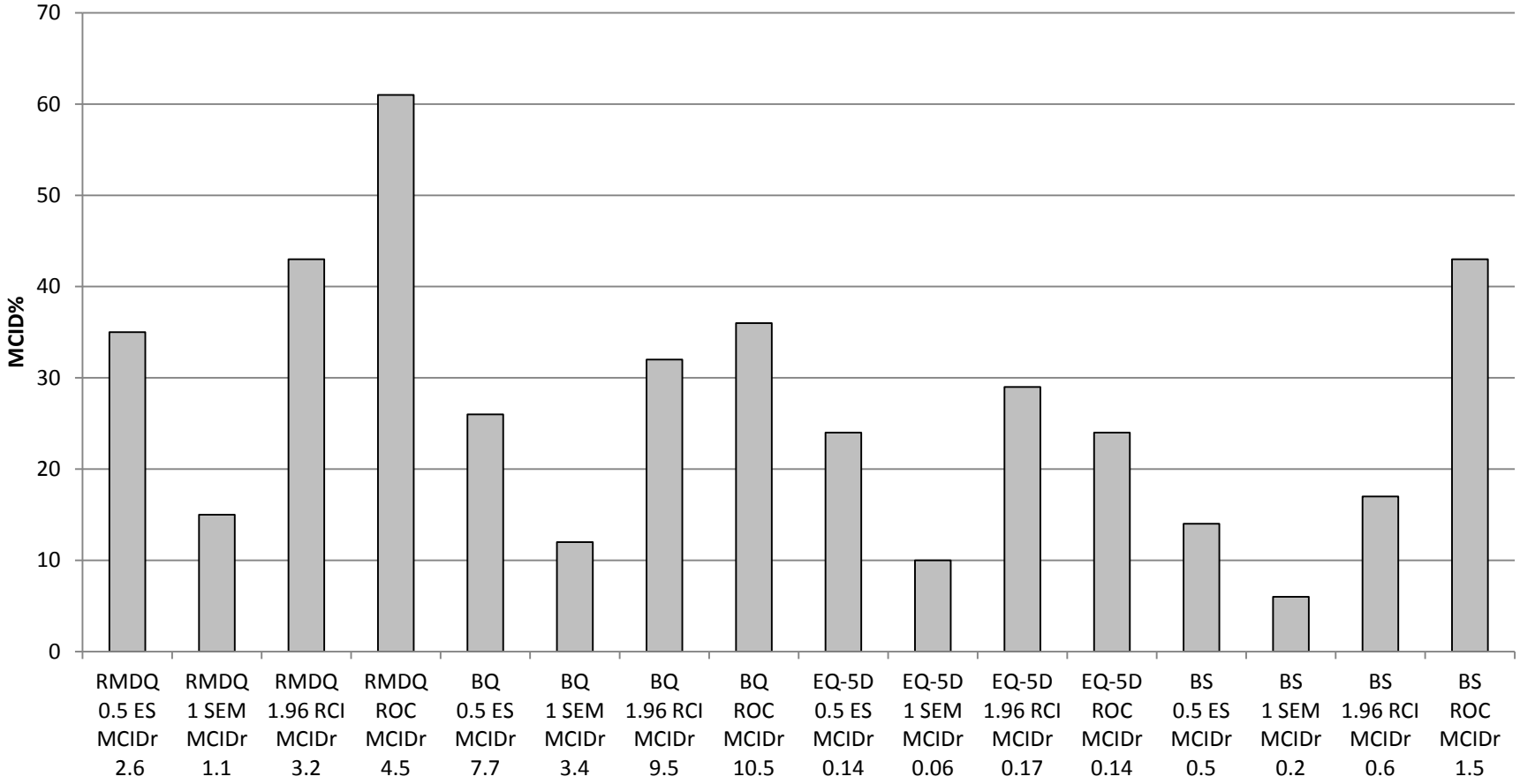

Figure 7.4: Percentage minimal clinically important difference (MCID%) for the Roland-Morris Disability Questionnaire (RMDQ), Bournemouth Questionnaire (BQ), EuroQol-5D (EQ-5D) and bothersomeness scale (BS) using four methods: 0.5 Effect Size (ES); 1 Standard Error of Measurement (SEM); 1.96 Reliable Change Index (RCI); and Receiver Operating Characteristic (ROC). Note: MCIDr = Raw minimal clinically important difference.

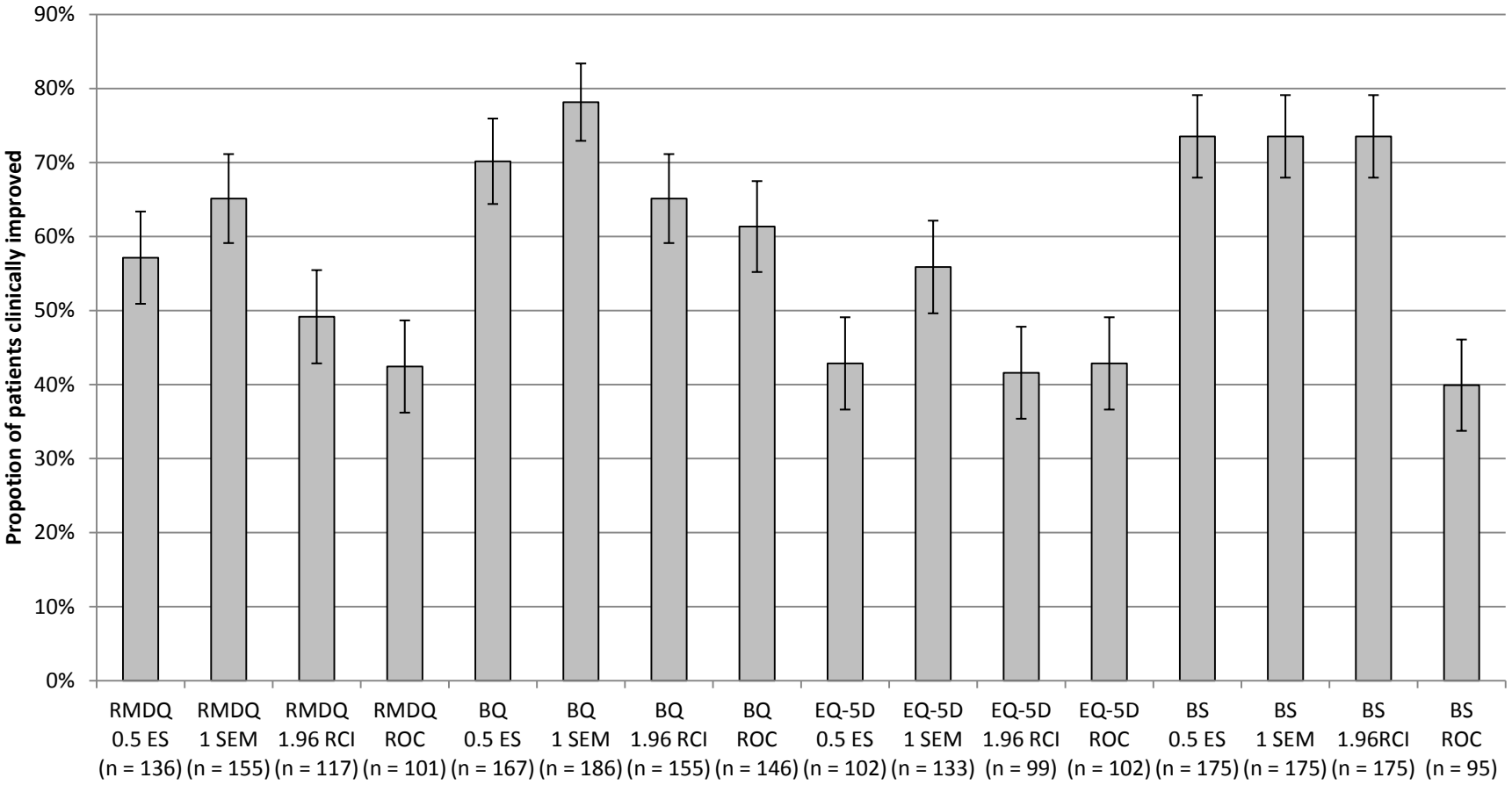

Figure 7.5: Proportion and 95% CI of patients clinically improved for the Roland-Morris Disability Questionnaire (RMDQ), Bournemouth Questionnaire (BQ), EuroQol-5D (EQ-5D) and bothersomeness scale (BS) using four thresholds: 0.5 Effect Size (ES); 1 Standard Error of Measurement (SEM); 1.96 Reliable Change Index (RCI); and Receiver Operating Characteristic (ROC).

In order to assess the diagnostic accuracy of the different thresholds of clinical improvement, each of them was plotted on a ROC graph against the criterion of clinical improvement, i.e. patients who selected the categories either 'much improved' or 'completely recovered' on the GPE scale (Figure 7.6). The agreement between patients categorised as clinically improved using the GPE scale and the cut-offs was generally poor (Cohen's Kappa coefficient ranging from 0.28 to 0.36). The general trend was for cut-offs to have moderate sensitivity and specificity, with the 0.5 ES, 1 SEM and 1.96 RCI cut-offs tending to be more sensitive (0.57–0.90) than specific (0.49–0.85), and the ROC cut-offs tending to be more specific (0.63–0.91) than sensitive (0.52–0.73).

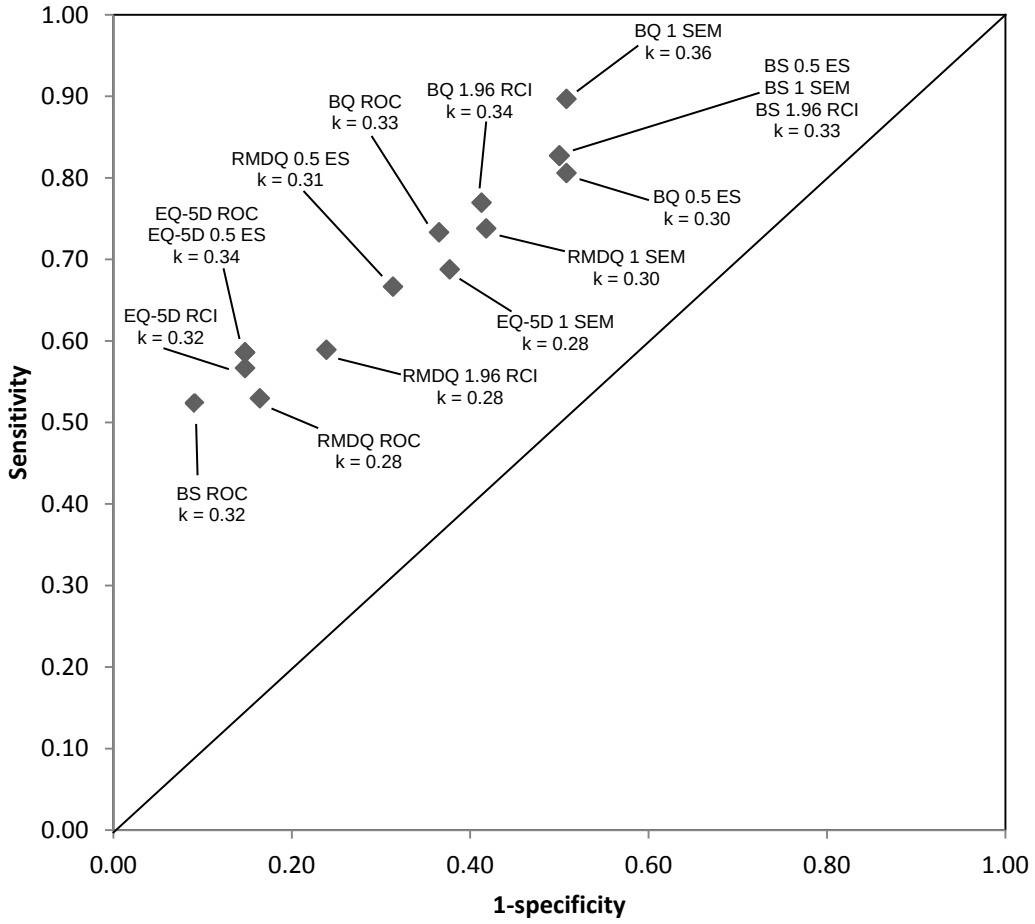

Figure 7.6: Receiver operating characteristic plot depicting the sensitivity and 1-specificity for the 0.5 Effect Size (ES), 1 Standard Error of Measurement (SEM), 1.96 Reliable Change Index (RCI) and Receiver Operating Characteristic (ROC) threshold approaches against the external criterion of clinical improvement (i.e. patients categorised as clinically improved on the Global Perceived Effect scale). Note: k = Cohen's Kappa statistic; RMDQ = Roland-Morris Disability Questionnaire; BQ = Bournemouth Questionnaire; EQ-5D = EuroQol-5D; BS = Bothersomeness scale.

Lifestyle changes are shown in Table 7.5. An increase in awareness of early warning signs of back pain, specific exercises for back pain, care when lifting and awareness of posture was most frequently reported, with these variables being rated as 'increased' by 136 to 181 (57% to 76%) of the patients at follow-up. Fewer patients reported an increase in rest and general physical activity/exercise, with 60 and 85 (25% and 36%) of the patients at follow-up rating these variables as 'increased' respectively.

Table 7.5: Lifestyle changes in 238 participants.

Variable		
Awareness of early warning signs of back pain	Increased	136 (57)
	No change	76 (32)
	Decreased	2 (1)
	Missing	24 (10)
Rest	Increased	60 (25)
	No change	145 (61)
	Decreased	6 (3)
	Missing	27 (11)
Specific exercises for back pain	Increased	157 (66)
	No change	65 (27)
	Decreased	2 (1)
	Missing	14 (6)
General physical activity/exercise	Increased	85 (36)
	No change	112 (47)
	Decreased	16 (7)
	Missing	25 (11)
Care when lifting	Increased	160 (67)
	No change	61 (26)
	Decreased	1 (< 1)
	Missing	16 (7)
Awareness of posture	Increased	181 (76)
	No change	45 (19)
	Decreased	0
	Missing	12 (5)

Values are frequency (%).

7.3.4 Patient experiences of care

Patient experiences of the process of care are shown in Table 7.6. Of the patients at follow-up, 129 (54%) rated the chiropractic care for their low back pain as 'very helpful' and a minority of these patients (12, 5%) rated this care as 'unhelpful' or 'very unhelpful'. The practitioners' attributes (i.e. time and explanations given by chiropractor as well involvement in decisions about care) were most frequently perceived as very good, with these variables being rated as 'very good' in 157 to 168 (66% to 71%) cases. Only rarely (6 cases, 3%) were practitioners' attributes rated as 'unhelpful'.

Patient experiences of the safety of care are given in Figure 7.7. Of the patients at follow-up, 125 (52%) experienced adverse events to care (i.e. worsening of their back pain, stiffness, soreness and/or general discomfort immediately or shortly after the chiropractic treatment visits). A minority of these patients (13, 5%) reported that they were unable to carry on with their usual activities and/or work as a result of these events.

Table 7.6: Patient experiences of the process of care in 238 participants.

Perceived helpfulness of care	Very helpful	129 (54)
	Helpful	67 (28)
	Don't know	30 (13)
	Unhelpful	9 (4)
	Very unhelpful	3 (1)
	Missing	0
Percentage (95% CI) of patients who rated perceived helpfulness of care as 'very helpful'		54 (47.9 to 60.5)
Rating of chiropractor giving the patient enough time	Very good	159 (67)
	Good	61 (26)
	Don't know	12 (5)
	Unhelpful	6 (3)
	Very unhelpful	0
	Missing	0
Percentage (95% CI) of patients who rated the chiropractor as 'very good' at giving enough time		67 (60.9 to 72.8)

Values are frequency (%) unless stated otherwise.

Table 7.6 *(continued)*: Patient experiences of the process of care in 238 participants.

Rating of chiropractor giving the patient an explanation for their back pain	Very good	168 (71)
	Good	57 (24)
	Don't know	7 (3)
	Unhelpful	6 (3)
	Very unhelpful	0
	Missing	0
Percentage (95% CI) of patients who rated the chiropractor as 'very good' at giving an explanation about their back pain		71 (64.8 to 76.3)
Rating of chiropractor involving the patient in decisions about care	Very good	157 (66)
	Good	61 (26)
	Don't know	14 (6)
	Unhelpful	6 (3)
	Very unhelpful	0
	Missing	0
Percentage (95% CI) of patients who rated the chiropractor as 'very good' at involving them in decisions about care		66 (60.0 to 71.9)

Values are frequency (%) unless stated otherwise.

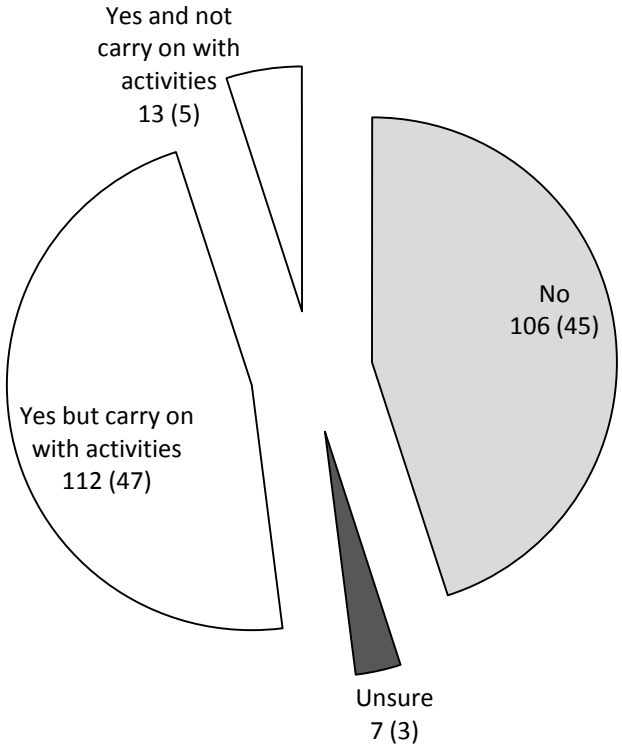

Figure 7.7: Frequency (%) patient experiences of the safety of care in 238 participants, i.e. adverse events.

7.3.5 Health care costs and usage

Costs of care

Costs during the 3-month study period are shown in Table 7.7. The mean total cost of care was £481.83 (95% CI = 333.17 to 639.42) per patient. Indirect costs (i.e. time off work) were the most important contributor to total costs (59.6%), and costs of chiropractic visits the second most important contributor, which accounted for nearly one-third of total costs (32.8%). Other health care usage including practitioner visits, medical procedures and diagnostic imaging were responsible for a small proportion of total costs ranging from 0.4% to 1.6%.

Health care usage

The mean chiropractic consultation rate for back pain was 5.9 per patient (SD = 4.03, range = 1-25 visits) for the 3-month study period. Two-thirds (33%) of the patients visited their chiropractor over six times during this period and accounted for 59% of all visits (n = 1352 visits).

Other health care use is shown in Figure 7.8. General practitioners were seen for back pain by 44 (18%) of the patients at follow-up, and the number of patients attending the hospital accident and emergency department, physiotherapist and medical specialist for back pain ranged from 9 to 15 (4% to 6%). Diagnostic radiology and MRI/CT scans of the back were received by 22 (9%) and 11 (5%) patients respectively. An injection into the spine was performed on one occasion only, and no back surgery or overnight stay in hospital was required by any patient in the study.

One hundred eighty-seven (79%) of the patients at follow-up were in paid employment and 27 (14%) of these were on sick leave for back pain for 26 (SD = 31.6, range 1-95) days on average during the study period, with high utilisers ($\geq$ 5 days) accounting for 97% of all days of sick leave (n = 704 days) taken by patients for back pain within the 3-month period of the study. Disability/incapacity benefits for back pain were only applied for on a single occasion.

Change in pain medication for back pain during the study period is given in Figure 7.9. One hundred and forty-four (61%) of the patients at follow-up reported never or

hardly ever using pain medication for back pain during the study period, and 60 (25%) of the same patients reported their use of this medication had reduced since completing the first questionnaire.

Table 7.7 Mean costs of care (in £) during 3 months in 229 patients.

	Mean (95% CI)	**% of total costs**
Direct costs	**194.47 (174.65 to 215.19)**	**40.4**
Chiropractic consultations	157.99 (145.02 to 171.91)	32.8
General practitioner consultations	6.60 (4.87 to 8.33)	1.4
Outpatient hospital visits to A & E department	1.93 (0.86 to 3.21)	0.4
Outpatient hospital visits to a physiotherapist	4.72 (1.97 to 7.47)	1.0
Outpatient hospital visits to medical specialist	7.76 (3.88 to 11.65)	1.6
Overnight stay in hospital	0	0
Radiographs (X-ray)	5.85 (3.44 to 8.56)	1.2
MRI/CT scans	7.07 (3.54 to11.32)	1.5
Injections into spine	2.54 (0.00 to 5.08)	0.5
Low back surgery	0	0
Indirect costs (i.e. time off work)	**287.36 (152.95 to 429.05)**	**59.6**
Total costs	**481.83 (333.17 to 639.42)**	**100**

Ninety-five percent confidence intervals (95% CI) are drawn from bootstrap analysis. Nine of the 238 participants at follow-up (4%) had incomplete cost data and were not included in the cost calculation. A & E = accident and Emergency. MRI/CT = Magnetic Resonance Imaging/Computed Tomography.

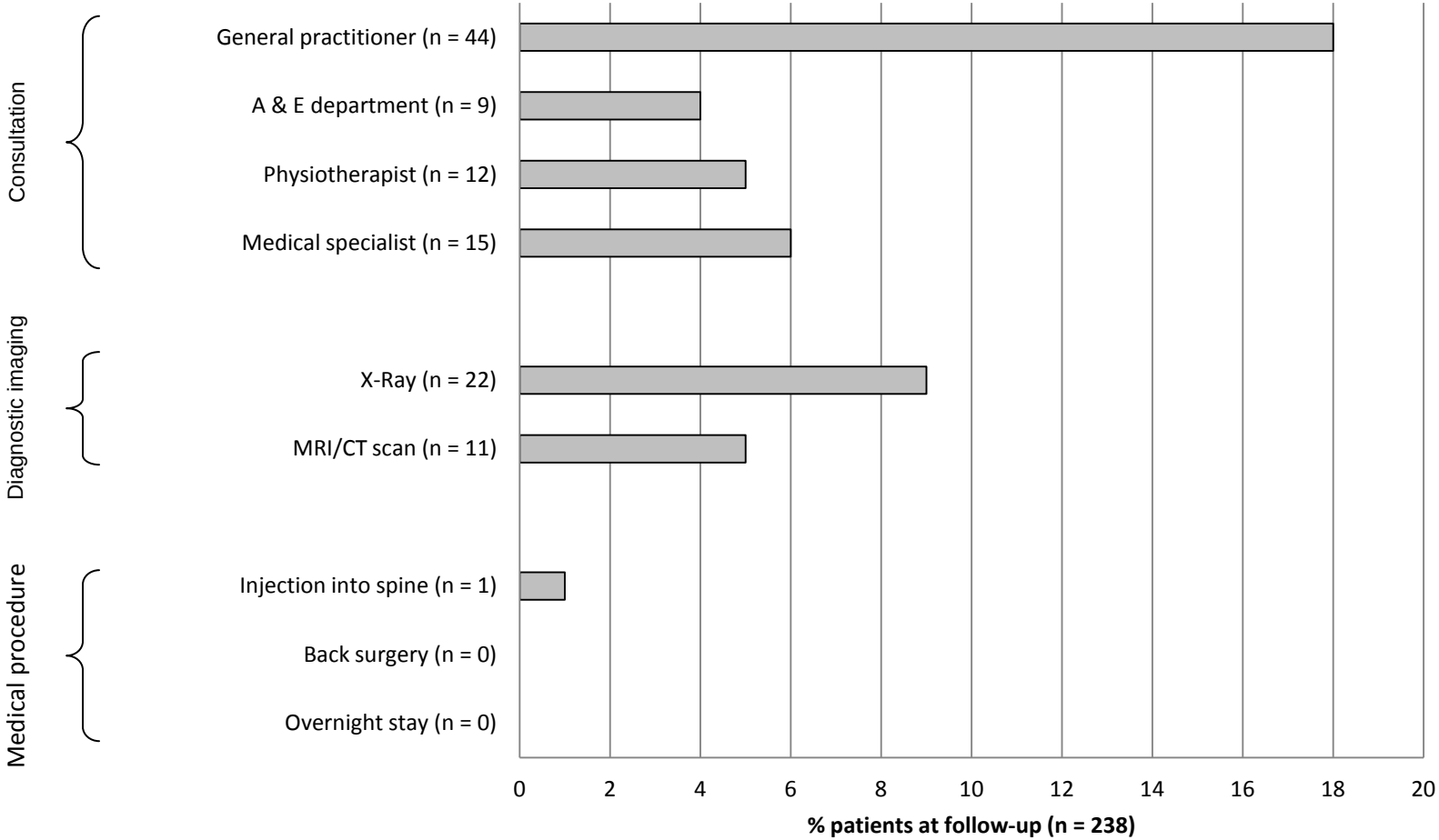

Figure 7.8: Other health usage in 238 participants.

Note: A & E = accident and emergency; MRI/CT = magnetic resonance imaging and computed tomography.

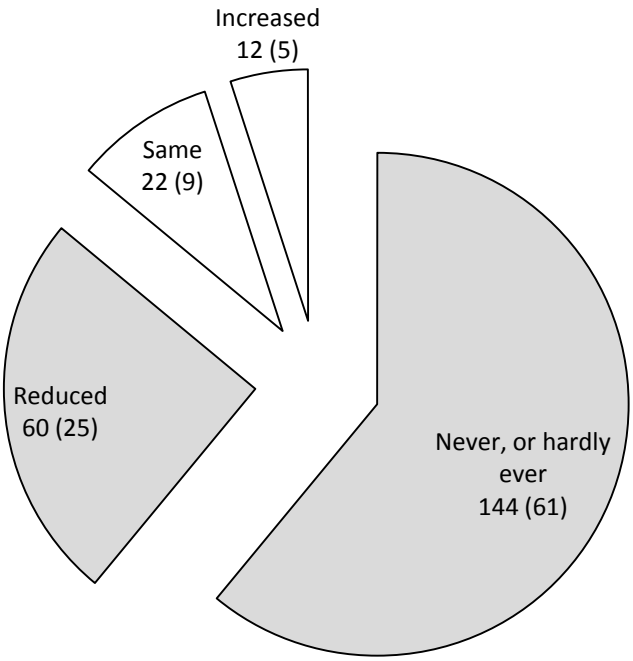

Figure 7.9: Frequency (%) change in pain medication usage (i.e. pain killers) for back pain during three months in 238 participants.

7.3.6 Evaluation of data collection instrument

Responsiveness of health status measures

The responsiveness of the health status measures contained in the data collection instrument is shown in Table 7.8. The effect sizes, depicting internal responsiveness or sensitivity to change, in increasing order, were 0.77, 0.87, 1.20 and 1.38 for the EQ-5D, RMDQ, BQ and bothersomeness scale respectively. The effect sizes of the BQ and bothersomeness scale were significantly different (non-overlapping confidence intervals) compared to those of the RMDQ and EQ-5D. With regards to external responsiveness, the AUC of ROC for all measures ranged from 0.73 to 0.78 and the differences between these values were non-significant when considering the confidence intervals, thus indicating that all measures had similar levels of ability to discriminate between clinically improved and clinically non-improved patients.

Table 7.8: Responsiveness of health status measures.

	Internal responsiveness	External responsiveness
	ES (95% CI)	***AUC of ROC (95% CI)**
RMDQ	0.87 (0.74 to 1.00)	0.75 (0.68 to 0.82)
BQ	1.20 (1.05 to 1.35)	0.77 (0.70 to 0.84)
EQ-5D	0.77 (0.62 to 0.92)	0.73 (0.66 to 0.81)
Bothersomeness scale	1.38 (1.22 to 1.55)	0.78 (0.72 to 0.84)

ES = Cohen's effect size. AUC of ROC = Area under the curve of Receiver Operating Characteristic. RMDQ = Roland-Morris Disability Questionnaire. BQ = Bournemouth Questionnaire. EQ-5D = EuroQol-5D. * Significant at $p < 0.001$.

Criterion validity of patient-reported number of visits made to the clinic

Criterion validity (accuracy) of patient-reported number of visits made to the clinic was evaluated by comparing the number of visits reported by patients to those reported in patients' files from 17 participating clinics. All 17 clinics returned the number of patient visits form, thus 89 participants (37% of patients at follow-up) were included in the validation sample used to determine the accuracy of patient-reported number of visits. No significant differences ($p < 0.05$) were found between the validation sample and the complete cohort in the distribution of clinical and demographic variables as well as baseline health status scores (Appendix 9). The power of the validation study was calculated to be adequate ($P = 0.83$; the recommended level being 0.80 or higher).

The mean number of visits reported in the follow-up questionnaire and in patient files was 4.6 (SD = 2.91) and 5.3 (SD = 3.26) respectively. Under-reporting was seen in 39 patients (44%) and over-reporting in only 13 patients (15%), with a mean of 0.6 (bootstrap 95% CI = 0.27 to 1.02) of additional visits reported in patient files (Wilcoxon signed-rank test, $p < 0.001$). In terms of economic significance, a difference of approximately 1 visit per patient would result either in an increase or decrease of the total costs in this study by 5%.

A Bland and Altman plot of the differences between methods (patient file – patient-report) versus mean values of the two methods is shown in Figure 7.10. The

differences between methods ranged between -5 and 8 visits (i.e. a negative value indicates patient over-reporting of visits), and 93% of the values were located between -3 and 3 visits, indicating that the level of agreement was inadequate. The plot also illustrates the fact that patients tended to under-report visits as the majority of the points were located above zero. In addition, the graph shows an increase in the variability with an increasing number of visits, with a significant upward bias indicating a trend towards under-reporting with increasing number of chiropractic visits in the previous three months (Spearman correlation coefficient = 0.295, $p < 0.01$).

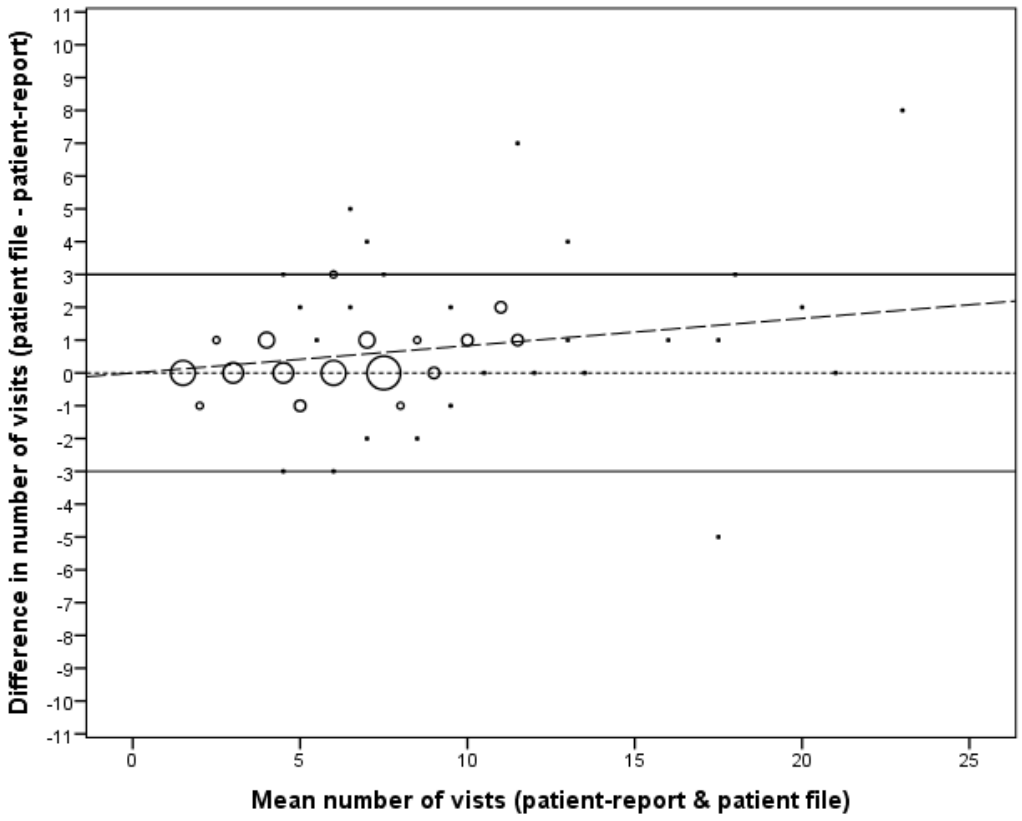

Figure 7.10: Bland and Altman plot comparing the number of chiropractic visits as determined by patient-report and patient file. The solid lines indicate the limits within which 93% of the differences lie, the wider dashed line represents the regression line, and the dotted line is drawn at zero (exact agreement). The size of each bubble is proportional to the number of patients with the corresponding x and y values.

Construct validity of measuring complete recovery from low back pain using construct-specific questions

Construct validity of measuring complete recovery from low back pain using construct-specific questions (i.e. acceptable quality of life, no disability and no pain for a whole month) was assessed by comparing patients categorized as completely recovered using these questions with those who selected the category 'completely recovered' on the GPE scale. Cohen's Kappa coefficient was 0.70 ($p < 0.001$), indicating good overall agreement between the two methods of measuring complete recovery from low back pain. A 2x2 contingency table was constructed (Table 7.9) for both methods of determining complete recovery so as to provide more detail about misclassified cases. This table showed that the majority of patients completely recovered from low back pain (i.e. as per GPE) were correctly classified as such by the construct-specific method of determining complete recovery (positive percent agreement = 88.9%), and that an approximately similar proportion of patients not completely recovered from low back pain were correctly classified as such by this method (negative percent agreement = 89.5%).

Table 7.9: Positive percent agreement (PPA) and negative percent agreement (NPA) of construct-specific method of determining complete recovery from low back pain.

		Global Perceived Effect i.e. patients categorised as 'completely recovered'		
		Recovered	Not recovered	Total
Construct-specific method i.e. positive response to three questions about pain, usual activities and quality of life	Recovered	40	20	60
	Not recovered	5	170	175
	Total	45	190	235

PPA (relative to Global Perceived Effect) = 88.9% (40/45)

NPA (relative to Global Perceived Effect) = 89.5% (170/190)

Three of the 238 participants at follow-up (1%) were not included in the agreement calculation due to incomplete data.

Questionnaire feedback

Questionnaire feedback results are given in Table 7.10. Nearly all of the patients at follow-up agreed or strongly agreed that the questions were clear and easy to answer (229, 96%) and that completion of the questions was not too disruptive or time consuming (233, 98%). The majority of the patients at follow-up agreed or strongly agreed that the questions were relevant to them and their back pain (202, 85%).

Table 7.10: Questionnaire feedback in 238 participants.

Variable		
Overall, the questions were clear and easy to answer	Strongly agree	109 (46)
	Agree	120 (50)
	Don't know	3 (1)
	Disagree	5 (2)
	Strongly disagree	0
	Missing	1 (< 1)
Overall, the questions were relevant to me and my back pain	Strongly agree	76 (32)
	Agree	126 (53)
	Don't know	12 (5)
	Disagree	23 (10)
	Strongly disagree	1 (< 1)
	Missing	0
Overall, completion of the questionnaires was not too disruptive or time consuming	Strongly agree	114 (48)
	Agree	119 (50)
	Don't know	2 (1)
	Disagree	3 (1)
	Strongly disagree	0
	Missing	0

Values are frequency (%).

7.4 Discussion

The present study intended to systematically document the quality and costs of care reported by low back patients three months after starting chiropractic care. It is unique in that it is the first attempt at combining information about health outcomes, patient experiences and costs of care in a single study conducted in routine everyday chiropractic practice in the United Kingdom. In addition, a secondary aim of the main study was to conduct an evaluation of the data collection instrument in terms of its suitability for purpose and ability to collect accurate and valid data. This evaluation was necessary as certain aspects of the instrument had not been used previously, and its performance in real-life clinical practice had to be determined before the main study could proceed.

The response rate at follow-up was reasonable and in line with that obtained in other observational studies conducted with chiropractic patients using postal follow-up (ranging from 54% to 63%).[230, 265-267] Quality of care research by the British National Health Service, using a similar design to the present study, showed comparably higher response rates (ranging from 64% to 90%) in patients undergoing surgical procedures.[268] This discrepancy may be explained by surgical procedures having a greater impact on people's lives and requiring longer follow-up than chiropractic care, thus perhaps encouraging a larger number of patients to respond to a follow-up questionnaire.

The typical low back pain patient attending a chiropractic clinic, according to published observational studies, is middle-aged, male and female in equal proportions and suffers from acute or sub-acute symptoms (< 3 months).[72, 73, 226, 230, 231, 266, 267, 269] The characteristics of the patients participating in the present study reflected these findings except for the duration of the presenting episode of low back pain. Indeed, the proportion of patients suffering from chronic low back pain (> 3 months) was markedly higher than that reported in other multi-centre studies conducted in Norway, Denmark and Switzerland (ranging from 20% to 36%).[72, 73, 230, 269] These controversial findings may be explained by the fact that chiropractic

care generally constitutes an out-of-pocket expense for patients in the United Kingdom, thus visiting a chiropractor for low back pain may have been a last resort option for many patients.

In general, patients who enrolled in the present study improved markedly on the BQ and RMDQ in the first three months of care and had low levels of pain and disability at the end of the 3-month study period. These findings are in line with two recent papers including a systematic review and a meta-analysis of the course of low back pain in patients treated by general practitioners, chiropractors, physiotherapist and specialists.[270, 271] According to these studies, acute/sub-acute and persistent low back pain patients typically show rapid improvements in pain and disability within the first few weeks of treatment.

Of particular interest was that on the BQ, in addition to pain and disability, psycho-social and cognitive-behavioural dimensions of the low back pain experience were also affected. Despite patients being considerably distressed at the initial consultation, fear avoidance beliefs on work and pain as well as anxiety were negligible at follow-up, indicating that cognitive appraisal of, and behavioural adaptation to, the pain experience had likely taken place during the study period. These findings are in opposition to research conducted by Langworthy and Breen in which it was concluded that chiropractic patients were not particularly distressed at the time of initial presentation.[265] Since the study by these authors was conducted in a single chiropractic clinic, its findings may not be generalisable to patients across a range of chiropractic clinics.

In contrast to pain and disability, there was little improvement over the study period in how much the pain bothered the patient, measured using a 5-point bothersomeness scale, and in patient health-related quality of life, measured using the EQ-5D. With respect to bothersomeness, these findings are not unique as similar low levels of improvement were found using a five-point bothersomeness scale in a previous study conducted on chiropractic patients with low back pain.[265] Dunn and Croft[39] have shown that the bothersomeness scale can be used to classify low back pain patients in primary care practice and that it is a valid measure of severity, being associated with measures of pain, disability and psychological health. While the bothersomeness scale has the potential to be a concise research instrument for low back pain, the

usefulness of this measure as an outcome measure in clinical practice and the significance of its scores have yet to be determined.

With regards to health-related quality of life, the rather small improvement noted over the study period on the EQ-5D compared to that on the RMDQ and BQ was likely the result of differences in scoring methods between measures. The scores produced by patients for the EQ-5D are transformed into utilities by means of tariffs or weights which have been estimated using preferences from a sample of the general population, while untransformed patient values are used for its counterparts.[191] Research comparing health-related quality of life measures, such as the EQ-5D, and condition-specific measures, such as the RMDQ and BQ, has shown that the difference in perspective between these measures can lead to dissimilar results.[44, 272]

To put the EQ-5D results into perspective, when health-related quality of life in the present 3-month study was transformed into QALYs, it corresponded approximately to one-fourth of the average QALYs per patient (0.659) in the manipulation group of the United Kingdom back pain exercise and manipulation randomised trial, which was conducted over a one year period.[273] Although comparisons between values of different studies should be made carefully, including health-related quality of life, it appears that participants fared equally well in a real-life clinical practice environment and in the environment of a clinical trial.

Two attempts were made at determining the clinical importance of the improvement in health outcomes in this patient sample. The first was the direct method of measuring improvement using patient perceived level of improvement on the GPE, and the second was the indirect method of measuring improvement using cut-off points in change scores, which enabled patients to be categorised as either clinically improved or clinically non-improved, on the RMDQ, BQ, EQ-5D and bothersomeness scale. Although the proportion of patients clinically improved determined using the first method was high, a wide range of proportions were obtained for the second method due to the variability in the cut-offs of clinical improvement within instruments and across measures, calculated by the distribution-based methods (i.e. 1.96 RCI, 0.5 ES and 1 SEM) and anchor-based method (i.e. ROC).

There appears to be controversy comparing cut-offs of clinical improvement in low back pain patients determined using different approaches, with some reports citing large variability in these values and others stating similarities.[145, 159, 160, 256, 274, 275] These opposing findings may be due to the fact that the threshold of clinical importance is population and context specific.[103, 107] For instance, Norman et al.,[159] who concluded that, in most cases, the cut-off of clinical improvement appeared to be approximately half a standard deviation, conducted their research with patients suffering from chronic conditions. Conversely, in the present study, the particularity of the sample including acute, sub-acute and persistent low back pain patients may have had an impact on the variability of the threshold of clinical improvement when determined using different approaches.

In addition to the variability in the estimates produced of the proportion of patients improved, low agreement was found when the patients categorised as improved using the cut-offs were compared to those considered clinically improved on the GPE scale (i.e. category 'much improved' and 'completely recovered'). These findings were similar to those of Beaton et al.[274] (low to moderate agreement) and may be the result of inherent differences between methods. Indeed, when the proportion of patients improved is determined using the GPE scale, it is based on individual patient reports of improvement, whereas when this proportion is determined using health status cut-off points, it is based on group change scores, hence not taking into account individual patient variability.[276] In spite of this limitation, the use of cut-offs of clinical improvement is recommended as such thresholds are useful tools in making health status change scores more readily interpretable.

In terms of diagnostic accuracy of the cut-offs, when using the GPE as an external criterion of clinical improvement, the ROC method generally yielded the most specific estimates of the proportion of patients clinically improved. In selecting a cut-off method with high specificity, the probability of false-positive values is reduced, and the certainty that patients have clinically improved if the change score exceeds the cut-off is increased.[276] In chiropractic practice, typically a wait-and-see policy prior to referral for surgery does not harm, thus rendering conservative cut-offs desirable, such as those determined using the ROC method. In addition, when contrasted to distribution-based methods (i.e. 0.5 ES, 1 SEM and 1.96 RCI), the ROC

method offers the advantage of being clinically relevant to patients because an external criterion based on patient opinion is used.[102, 103, 107, 275-277] Given these factors, if a single cut-off method had to be recommended for use in patients undergoing routine treatment for low back pain, the ROC method would be favoured.

In addition to suggesting the best available method for determining how many patients have clinically improved, it may useful to select a single health status measure for use in routine outcome research so as to streamline results between studies as well as to ensure the relevance of findings to patients, clinicians and commissioners. If a single low back pain health status measure were to be recommended based on the results of this study, a sensible option would be the BQ. When contrasted to the RMDQ, EQ-5D and bothersomeness scale, the BQ is the only measure that offers comprehensive information about a number of dimensions relevant to the low back pain experience including sensory, functional, affective and cognitive/behavioural dimensions.[41]

In terms of responsiveness, the results of this study also favoured the BQ. Although the health status measures included in the present study had similar discriminative performance between patients that were clinically improved and those that were not, there were important differences between measures with regards to their capacity to detect change in health status over time (i.e. sensitivity to change). Indeed, the BQ was significantly more sensitive to change than the RMDQ and EQ-5D, and these findings were in accordance with previous reports on the responsiveness of the BQ, RMDQ and EQ-5D.[29, 41, 44, 50, 59] Despite its low responsiveness, the EQ-5D remains an important addition in studies assessing health care costs since it enables the calculation of QALYs.[162] With regards to the bothersomeness scale, its sensitivity to change was comparable to the BQ; however, the scale width of the bothersomeness scale was insufficient as three out of four health status cut-offs were less than one bothersomeness scale point, hence any improvement would be considered clinically important on this measure.

The calculation of the proportion of patients clinically improved is only one aspect of the picture. This figure provides no information about patients whose episode of low back has resolved, or in other words the proportion of patients recovered from low back pain. In the present study, the proportion of patients considered recovered at

three months (i.e. acceptable quality of life, no disability and no pain for a whole month) was markedly inferior to the proportion of patients clinically improved. One explanation for this paradox may be mostly the chronic patients that participated in the present study for whom the study period may have been too short to fully recover from their condition.

A second reason for the discrepancy between the proportion of patients categorised as clinically improved and recovered may be the stringent criteria used to define recovery from low back pain. Typically, in previous studies, patients were considered as recovered if they had been free of low back pain for a whole month preceding follow-up data collection points, which is a defintion based on the work by de Vet and colleagues.[80] Henschke et al.[81, 85, 87, 228, 229] took this defintion further by considering patients as recovered if, in addition to being pain-free for a whole month, they had no disability for a similar period. In the present study, the decision to add a third domain (i.e. quality of life) to those of pain and disability was based on the findings of a qualitative study conducted by Hush et al.[23] in which patients considered quality of life an important entity of low back pain recovery.

The construct validity of the definition of recovery from low back pain was evaluated by comparing patients that had no pain, no disability and an acceptable quality of life for a whole month preceding the second data collection point to those who scored 'completed recovered' on the GPE scale. Although high agreement was found between both methods of determining the proportion of patients recovered, a minority of patients were either misclassified as recovered or not recovered using the definition of recovery. The idiosyncrasy of the concept of recovery from low back pain may be at the origin of these findings.[81] For some patients, the mere absence of pain and disability as well as the achievement of acceptable quality of life may be insufficient to consider themselves recovered, and for others, these critieria may be irrelevant as they may have adjusted to living with the disorder or redefined the meaning of recovery by accommodating the pain as part of their lives. Taking into account the individualistic nature of the concept of recovery as well as the similarites between recovery as determined by the definitons and the GPE, if a decision needed to be made regarding the mesurement of this concept in clinical practice, the more concise GPE method would be recommended.

Despite the stringent criteria used to define recovery, the proportion of patients recovered from low low back pain in the present study was close to the pooled estimate (33%) of the same information after the first three months of primary care reported in a recent systematic review of 11 studies.[278] However, when patients considered recovered at any time during the study were compared against those still recovered at follow-up (i.e. recurrence of low back pain), dispartities were found between the present study and the literature. Indeed, while a fairly low rate of recurrence after the presenting episode of low back pain was found in the present study, moderate to high rates of recurrence were reported in published studies (ranging from 33% to 69%).[71, 74] This discrepancy may be explained by the relatively short duration of the present study which may have been insufficent for some patients to achieve a state of no pain, no disability and an acceptable quality of life for a whole month (i.e. recovery) followed by the onset of a new episode of low back pain (i.e. recurrence).

The final aspect of the outcome evaluation of the present study involved the determination of lifestyle changes that patients made during the study period. The answers to these questions showed that although specific activities for back pain, such as tailored exercise, postural alteration and awareness of back pain signs were increased, activities to promote general health, such as general exercise and rest, remained unchanged. These findings are to be expected as the goal of chiropractic treatment, in principle, is to manage the patient's complaint and not to improve their general wellness. However, the rate of missing data for these questions was relatively high compared to other variables, indicating that patients may have felt that these questions were unclear or irrelevant to their condition.

In addition to determining how well the patients were doing (i.e. health outcomes), it was important to investigate the patients' experience of the care provided. Although health outcomes are considered the most important indicator of the quality of care, patient experiences can offer information about the process and safety of care, which in turn may influence outcomes and hence the quality of care.[12] With regards to the process of chiropractic care, published studies have shown that this treatment option is generally welcomed by patients for low back pain, with the proportion of patients who consider chiropractic care for this condition as 'very helpful' ranging from 53%

to 66%.[279-281] The values of the present study pertaining to perceived helpfulness of care fell within these ranges.

Previous studies comparing perceived helpfulness of chiropractic care, general practitioner care and other therapies for the treatment of low back pain showed that chiropractic care was generally associated with the same, or a greater, level of perceived benefit as other forms of treatment for this condition.[279-282] Although this may appear as an important discovery, some authors have criticised generic scales, such as the one used to assess perceived helpfulness of care, for being unspecific and, therefore, patient ratings may be biased by factors irrelevant to the process of care.[195-197, 208, 283, 284] This concern was taken into account by evaluating, in addition to perceived helpfulness of care, specific aspects of the process of care. The aspects evaluated pertained to the practitioner's ability to communicate information and advice to patients as well as to interact with them, which are considered by patients as the most important determinants of a positive experience of care.[211-214, 285, 286]

These practitioner attributes, including time and explanations given by the chiropractor as well as the patient's involvement in decisions about care, were rated as 'very good' by the majority of patients in the present study. The same aspects of the process of care, in the GP Patient Survey 2011-2012, were rated as 'very good' by a comparatively lower proportion of participants drawn from a random sample of patients attending general practitioner clinics in the United Kingdom (values ranging from 47% to 52%).[216] However, these differences between studies should be interpreted carefully as they were small in magnitude and the patients seen by chiropractors and general practitioners are typically not the same. Moreover, the response rate of the GP patient survey 2011-2012 was fairly low (38%).

The safety of chiropractic care and manipulative therapy in general, which is the main treatment procedure used by chiropractors, has been the topic of much debate, with some scientists arguing that these therapies may be unsafe.[287] However, the findings of the present study pertaining to patient experiences of adverse events, which were defined as worsening of back pain, stiffness, soreness and/or general discomfort immediately or shortly after the chiropractic treatment visits, showed that these assumptions may be unfounded. Indeed, the findings of the present study were in accordance with previous research showing that adverse reactions in patients

receiving chiropractic care are common, but are typically benign and have little to no influence on activities of daily living.[164, 165, 167, 220]

The uniqueness of the findings on adverse events in the present study lies in the fact that these data were collected from patients as opposed to practitioners from whom this information has typically been gathered in the past. Some authors have argued that studies relying on practitioners to report data on adverse reactions resulting from treatment may suffer from underreporting, perhaps due to practitioners fearing criticism.[218, 219] Since the findings on adverse events of the present study were in line with previous research conducted using practitioner-reported data, it appears that underreporting by practitioners may not be a concern when assessing data on adverse events in chiropractic clinics.

In order to enable the attribution of a monetary value to the health outcomes achieved, the costs of the services provided during the 3-month study period were monitored. Nearly the entirety of treatment costs (i.e. direct costs) referred to chiropractic visits since other health care and diagnostic imaging were only used on few occasions. These findings are in accordance with the costing report accompanying the guidelines for the management of low back pain by the National Institute of Clinical Excellence.[238] This report concluded that few additional services would be required by the English National Health Service if low back pain patients were treated by manual therapists such as chiropractors.

One comparable study was found on the cost of low back pain in routine clinical practice, which was conducted in German general practitioner clinics by Becker et al.[288] In contrary to the present study, only a small proportion of treatment costs were attributed to primary practitioner visits (i.e. general practitioner), and the main contributor to these costs were visits to specialists and manual therapists as well as medication and diagnostic procedure usage. These disparities between studies in terms of other health care usage may be due to differences in study settings and patients. Indeed, there is evidence to support the fact that different types of patients are seen by general practitioners and chiropractors, with chiropractic patients tending to have fewer chronic conditions than general practitioner patients.[279]

With regards to the costs of lost productivity resulting from time away from work (i.e. indirect costs), the present study was in accordance with previous reports on the cost of health care for low back pain, showing that indirect costs are typically the most important contributor to total costs.[170] However, the findings of the present study differed to those of an observational study conducted in general practitioner clinics in that only a minority of patients took time off work for low back pain compared to nearly one-third of patients (32.5%) going on leave for this matter in the general practitioner study.[288] In the present study, the reasons for the importance of the contribution of indirect costs to total costs in spite of the low rate of leave may be twofold. First, indirect costs may have been unfairly weighted against total costs due the low cost of chiropractic treatment, and second, the few patients that took time off work may have taken prolonged sick leave for low back pain. There was evidence to support the latter as nearly all patients on sick leave due to low back pain took over 5 days off work for their condition.

Due to the fact that the accuracy of cost data on treatment visits in chiropractic clinics had not been evaluated previously, it was imperative to conduct such an analysis in the present study.[171, 172, 174-177] When the accuracy of the cost data on chiropractic visits was evaluated by comparing patient-reported number of visits made to the clinic and the same information reported in patients' files, low agreement was found between the two methods of determining these data. However, even if patient-reported data of chiropractic visits were more accurate, the use of this information is not likely to bias the results on costs unless there were systematic differences between patient-reported visits and visits as based on patient files.[173]

In the present study, there was evidence that this was happening, with patients tending to under-report the number of visits, particularly for higher numbers, by on average approximately one visit when compared to the number of visits reported in patient files. Whilst this difference between the two methods of data collection was statistically significant, it was not of economic significance as the change in total costs when varying the number of visits by ± 1 was minor. In addition, even if patient files and self-report were in exact agreement, it is uncertain whether the patient file represents the more reliable source of data on number of visits. Indeed, these data may have been omitted from files by mistake or recorded in such a form

that they were not easily accessible to the clinic staff responsible for returning the number of patient visits made to the clinic during the study period.

The present study had several limitations, with the principal limitation being that the data documented may not necessarily be the result of the treatment administered since the study design lacked a control group for comparison. Instead these data could be partly or entirely attributed to non-specific treatment effects including measurement error and the natural course of condition. However, the focus of the present study was in evaluating the quality and cost of care *per se*, irrespective of the effects, either specific or non-specific, of that care.

Bias in relation to patient selection and patient-report must be considered, such as chiropractors or clinic staff recruiting patients who are more likely to improve or who provide polite positive answers. To avoid arbitrary selection of patients by practitioners or clinic staff, consecutive sampling was indicated and the importance of recruiting patients consecutively was emphasized in the user guide mailed to participating chiropractors prior to the commencement of the study. To counteract patients from inflating responses, patients were not considered clinically improved unless they selected the category ‘much improved’ or ‘completely recovered’ on the GPE scale, and those who selected ‘slightly improved’ on this scale were not considered clinically improved.

Other limitations pertaining to patient responses are the possibility of recall bias and misattribution due to patients being unable to distinguish between low back pain-related procedures and others. Although the 3-month study period may have been too short for some patients to show improvement or recovery from low back pain, a period of more than three months may have increased recall bias, with some patients remembering costs and outcomes less well if they occurred early on in the monitoring period. Moreover, there was evidence of a difference in the patient characteristics of responders and non-responders at follow-up, which may have affected the generalisibility of the findings of this study.

Similarly, the practitioners that volunteered for inclusion into the study may have been a source of bias as 120 of the 1314 chiropractors (9%) that were members of the British Chiropractic Association at the time of data collection participated in the

study.[289] A selection bias may be present because practitioners willing to participate in research may be more focused on evidence-based care than non-participating chiropractors. In addition, due to patients being recruited from multiple practices, there was the possibility that patient data were clustered within practitioners. Such clustering effects would increase the width of the confidence intervals but would not affect the point estimates.[218] In a trade-off to maximize practitioner participation and compliance, the design of the present study precluded reported events from being linked to individual practitioners, hence clustering effects could not be evaluated.

Bias may not only arise from patients and practitioners, it may also originate from the measures selected for inclusion in the data collection instrument as each measure used may potentially lead to different results. In clinical trials, such bias is often reduced by investigating outcomes and other data by a large number of research tools. In order to maximize participation rates and the clinical relevance of results, the use of lengthy questionnaires that could interfere with the usual activities taking place in clinics and the daily schedule of participants was avoided. The results pertaining to the face validity of the data collection instrument confirmed that these goals were met because nearly all patients felt that completion of the questions was not too disruptive or time consuming, and that questions were relevant, clear and easy to answer.

The strengths of this study were the large study sample and the good quality of the data, with few questionnaires with faulty answers that had to be discarded and only few missing data. Additional strengths include the evaluation of costs of care and the use of strict definitions of low back pain recurrence and recovery. Positive aspects of the study design were that events in a real-life clinical situation were documented and that a wide variety of practitioners and patients were included in the study, thus making the results clinically relevant for those participating, and generalisable to others. Secondary gains of the study were that it allowed practitioners to participate in research without having to spend an excessive amount of time with the project, hence making them aware of the rigours associated with data collection and encouraging an interest in the study results, and in research in general.

CHAPTER 8

Conclusions and recommendations

The present study documented, likely for the first time, simultaneously the quality and costs of care in low back patients undergoing chiropractic treatment. The main findings of the study were that patients who presented with low back pain of varying duration improved markedly within the first three months of starting care, and expressed high levels of satisfaction with chiropractic treatment and with the encounter with their clinician. Chiropractic care was shown to be relatively safe, with common yet benign side-effects that had no significant effects on activities of daily living. Moreover, the costs of the health care provided during the study period were relatively low and few other health care professionals or procedures were used in conjunction with chiropractic care.

In order to provide additional information about the course of disease, data on low back pain recovery and recurrences were also assessed. These data revealed an important point which was that although the majority of patients showed marked improvements in health outcomes within the first three months of starting care, the rate of recovery from low back pain (i.e. full resolution of episode of low back pain) was considerably low during this period. In addition, recurrences of low back pain (i.e. onset of a new episode of low back pain following recovery from a previous episode) occurred in a number of patients who had recovered from the presenting episode of low back pain. These findings are consistent with those of previous research about the course of low back pain in primary care, showing that low back pain is a complex condition that has an untidy pattern of symptoms with incomplete recovery and potential recurrences in a relatively short space of time.

As part of this study, the data collection instrument was evaluated for its suitability for purpose and ability to collect relevant data from which a number of recommendations ensued. These recommendations pertained to the use of outcome measures for conducting observational research in clinical practice as well as the methods used to report patient improvement from these measures.

The findings of this study support chiropractic care as a treatment option for low back pain. If chiropractic care is provided as part of the National Health Service in the future for patients suffering from low back pain, it may be suggested that the workload on general practitioners could be eased, hence improving the quality of care and potentially reducing treatment costs. This might not only result from a redistribution of low back pain patients to other health care facilities but also from the provision of more specialised care.

Future research on the quality and costs of care in low back pain patients and others undergoing chiropractic care should consist of a large-scale questionnaire-based study using a similar design to the present one and taking into account the recommendations regarding data collection and reporting made in this study. Such research could be conducted in chiropractic clinics in the United Kingdom on a continuous basis, allowing for systematic collection and analysis of data. In order for this to progress the leadership of the chiropractic profession must recruit personnel whose role it is to build a national information database on the quality and cost of care and, perhaps, make data collection by chiropractors and their staff a compulsory aspect of membership. Research on the quality and costs of care should not only be conducted by the chiropractic profession but should also be expanded to related primary health care professionals, such as general practitioners and physiotherapists.

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Appendix 1: Pilot study documentation.

- User guide regarding data collection process
- Baseline and follow-up questionnaire
- Cover letter accompanying data collection pack –
  for the attention of chiropractors and clinic staff
- Cover letter accompanying follow-up questionnaire –
  for the attention of participants
- Number of patient visits form and accompanying cover letter –
  for the attention of chiropractors and clinic staff

USER GUIDE

1. What is this study about?

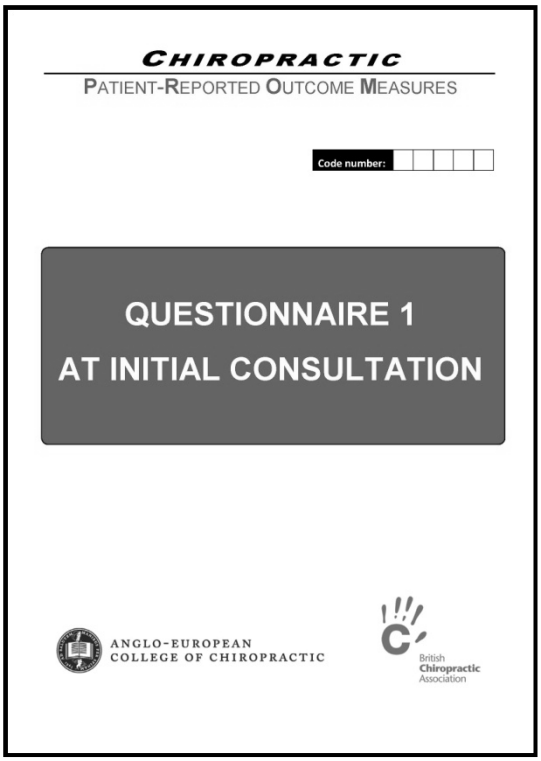
The purpose of the **C**hiropractic **P**atient **R**eported **O**utcome **M**easures **S**tudy (**C-PROMS**) is to develop two short questionnaires to collect routine information concerning outcomes and cost in chiropractic practices across the United Kingdom**.** This information is required to assess and improve the quality of chiropractic care and to inform patients, clinicians and third-party payers.

2. How is the study being done?

You or your staff will collect data (Questionnaire 1) from **10 consecutive eligible new patients,** who consent to participate in the study, presenting to your clinic for the **first time** with **low back pain**. Thereafter, patients will be sent a second questionnaire (Questionnaire 2) at three months by post. This second questionnaire will be sent directly from the Anglo-European College of Chiropractic, so there is no work involved for you or your staff. If your clinic is equipped with a computer booking system, you or your staff **may** be sent a form requesting the total number of treatments each of these patients received within this three month period. All your contact details will be kept confidential for the purposes of this study.

3. How long will the study last?

Starting from April 2010, patient recruitment will last until February 2011.



4. Setting up the study

Before data collection can start, the following should have happened:

- You should have received copies of Questionnaire 1 and a pre-paid return envelope for each copy.
- You should have read this User Guide and if you have staff (e.g. receptionist, practice manager) ensure all of them understand how to collect and submit data (they all should have read this User Guide).

NOW YOU ARE READY TO START DATA COLLECTION.

5. Patient eligibility criteria for participation in the study

To be eligible for participation in the study, patients must fulfil ALL of the following:

- ✓ Patients must **HAVE LOW BACK PAIN WITH OR WITHOUT LEG PAIN** as their main complaint
- ✓ Patients must be **18 years of age or older**
- ✓ Patients must **NOT HAVE** received treatment for their low back pain from a healthcare professional **EXCEPT FROM THEIR GP** in the **PAST 3 MONTHS**
- ✓ Patients must **NOT be pregnant**
- ✓ Patients must be **literate in English**

6. Patient recruitment

6.1. On the phone

You will recruit **10 CONSECUTIVE NEW PATIENTS** presenting with **low back pain**. When these new patients make an appointment at the clinic they should be told:

- "the clinic is currently taking part in a study about low back pain"
- "you will be given more information about the study when you arrive for your appointment so you can decide whether you want to take part or not"
- "there will be no change to your chiropractic treatment whether you want to take part or not"
- "we would like you to arrive 10-15 minutes early for your appointment to allow time for you to read the information about the study and complete the forms"

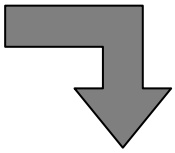
6.2. At the clinic

Please consider the following questions:

- **Is the patient eligible (refer to eligibility criteria) to enter the study?**

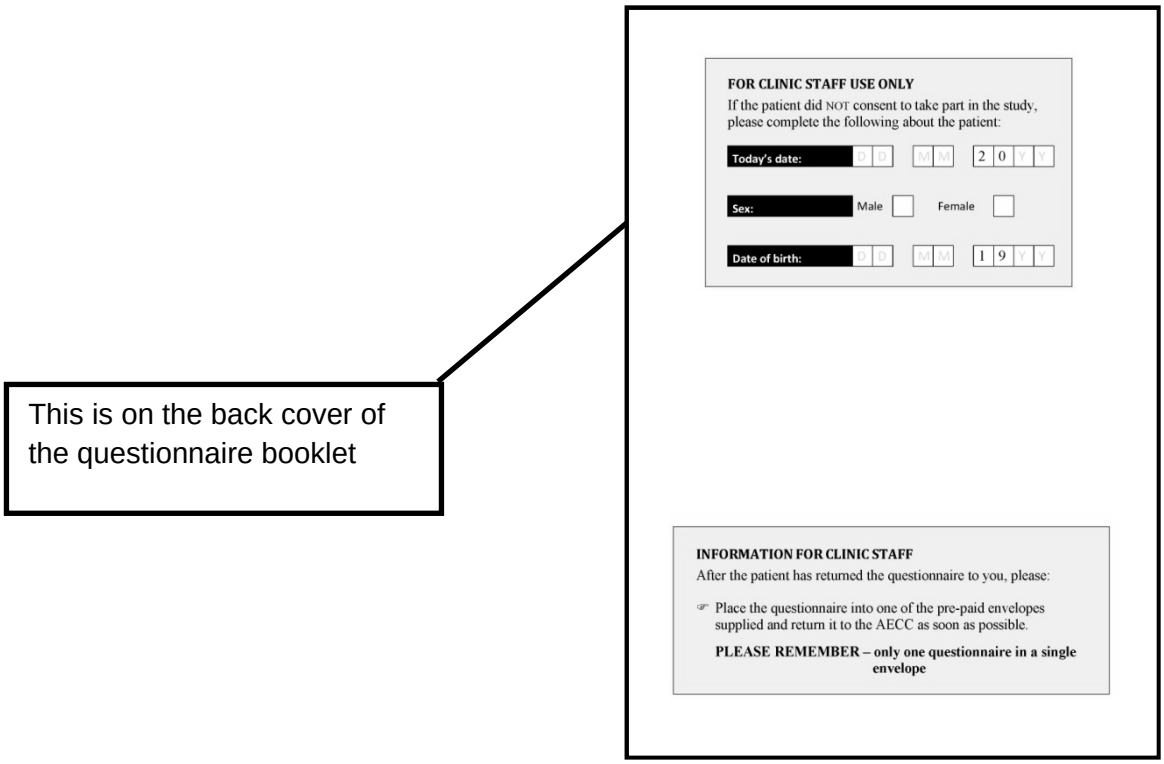
If they are **not eligible**, take no further action.

If they are **eligible**, then proceed to the next stage.



- **If eligible, then** please give them the questionnaire booklet (Questionnaire 1) and ask them to read the information at the start (page 1) and decide if they wish to complete the questionnaire. The questionnaire has been designed for patients to read and complete by themselves; you do not have to help the patient with the questionnaire. The patient now reads the information at the start of the Questionnaire (page 1).

- **If after reading the information the patient informs you that they DO NOT want to take part**, please complete the questions on the back cover of the questionnaire (see diagram below):



  - ✓ The booklet should then be put into one of the pre-paid envelopes provided and returned to the Principal Investigator at the AECC as soon as possible. You do NOT have to wait until all the data are collected (10 patients) to return each questionnaire.
    N.B. Even though the patient does not want to take part, this still counts as one of your 10 consecutive eligible patients.

- **If a patient decides they DO want to take part in the study, please ask them to proceed and complete the questionnaire. The patient must complete the questionnaire in the practice before any treatment and return it to you straight away. Then, please:**
  - ✓ Check that the patient's name and address have been completed on page 2 of the questionnaire.
  - ✓ Place the completed questionnaire into one of the pre-paid envelopes supplied and return it to the Principal Investigator at the AECC (one questionnaire in a single envelope) as soon as possible.

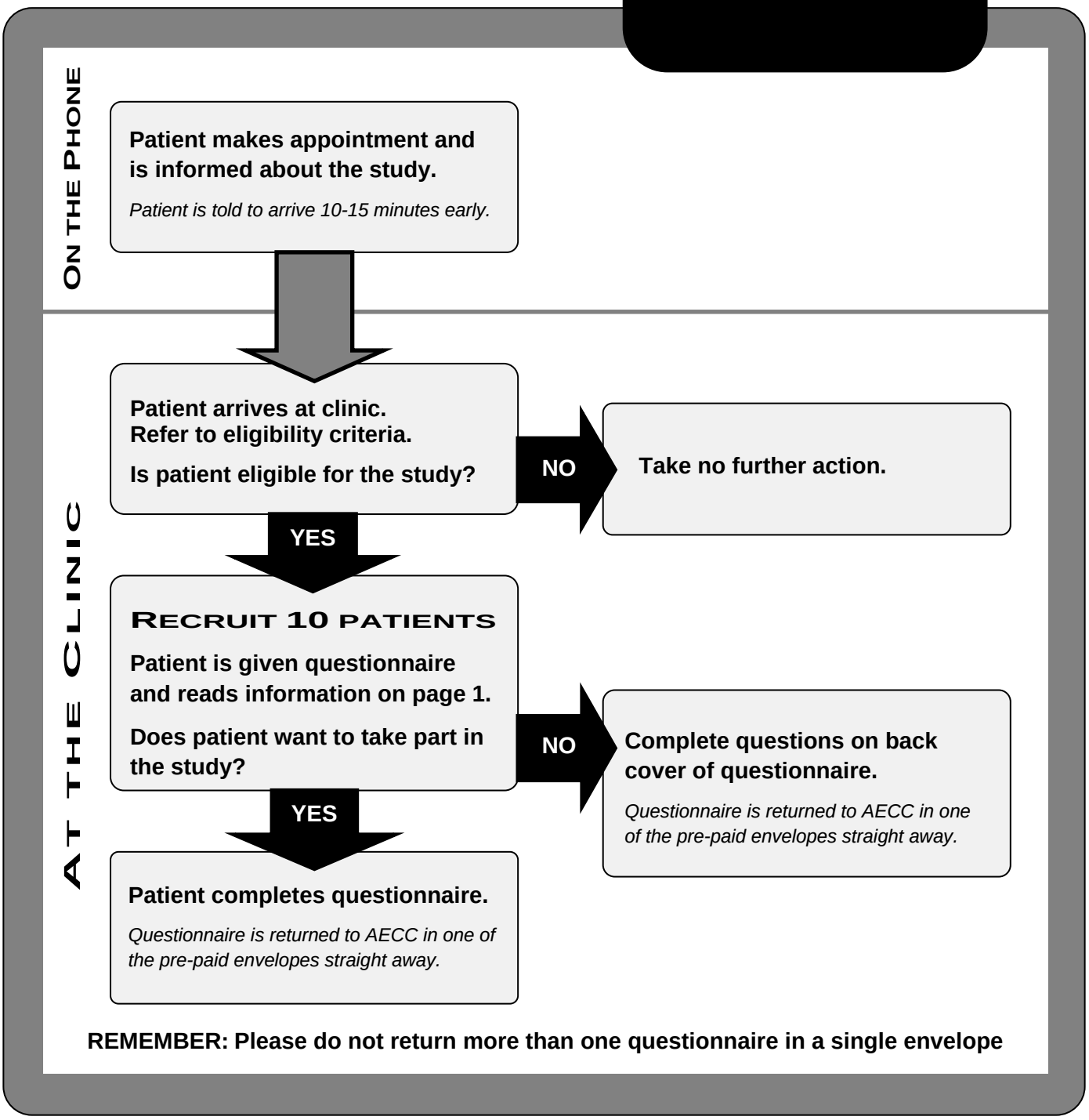
7. Want to know more?

Dr Taco Houweling (Principal Investigator): Tel: 01202 436234 / 079 31444501;
Email: thouweling@aecc.ac.uk

Professor Jennifer Bolton (Study Supervisor): Tel: 01202 436200; Email: jbolton@aecc.ac.uk

Dr David Newell (Study Supervisor): Tel: 01202 436200; Email: dnewell@aecc.ac.uk *Anglo-European College of Chiropractic (AECC), 13-15 Parkwood Road, BOURNEMOUTH BH5 2DF.*

Summary of information flow within C-PROMS



Acknowledgments: C-PROMS is funded by the British Chiropractic Association (BCA) and the Anglo-European College of Chiropractic (AECC). The study has been submitted and approved by the Ethics Sub-Committee of the AECC.

THANK YOU FOR YOUR TIME AND HELP WITH THIS STUDY.

CHIROPRACTIC

PATIENT-REPORTED OUTCOME MEASURES

Code number:					

QUESTIONNAIRE 1
AT INITIAL CONSULTATION

ANGLO-EUROPEAN
COLLEGE OF CHIROPRACTIC

British
Chiropractic
Association

INFORMATION AND YOUR CONSENT

What is the Chiropractic Patient-Reported Outcome Measures Study (C-PROMS)?

The purpose of this research study is to collect information in chiropractic clinics regarding your experiences of care and the costs of treatment. The information that patients provide is an important part of the way in which decisions are made regarding the delivery of healthcare services in the UK.

How is the study being done?

You will be asked to complete two questionnaires; each one will take about 10-15 minutes of your time. The first questionnaire you will be asked to complete today. The second questionnaire you will receive in the post in about 3 months time, which you will be asked to complete and then return in an enclosed stamped addressed envelope. In addition, we may ask your chiropractor the total number of treatments you have received over this 3 month period.

Who is undertaking this study?

Dr Taco Houweling is the Principal Investigator, and is conducting this study as part of a PhD funded by the Anglo-European College of Chiropractic and the British Chiropractic Association.

Why should I take part?

This study will help improve patient care in the future, from which you may benefit.

Do I have to take part?

Your participation is voluntary and you are free to withdraw at any time without giving any reason. Your chiropractic care is NOT affected either by your decision to participate or not, or by any decision to withdraw once you have started.

What will happen to the information I give?

All the information is strictly confidential and will NOT be divulged to your chiropractor. It will be used anonymously and only for the research study. Published reports will not refer to any individuals; your name and address is only required to enable us to send you the questionnaire at the 3 month follow-up. If we need to send you a reminder, we will do so by post, phone and/or email.

What now?

If you agree to take part please sign below and complete the questionnaire now. Otherwise, please hand back the questionnaire to the person who gave it to you.

I have read and understood the information given above and agree to take part in the study:

Signature:	Name (please print):	Date:

Want to know more?

Dr Taco Houweling (Principal Investigator): Tel: 07931444501; email: thouweling@aecc.ac.uk
Professor Jennifer Bolton (Study Supervisor): Tel: 01202 436200; email: jbolton@aecc.ac.uk
Dr David Newell (Study Supervisor): Tel: 01202 436200; email: dnewell@aecc.ac.uk

Anglo-European College of Chiropractic (AECC), 13-15 Parkwood Road, BOURNEMOUTH BH5 2DF.

THANK YOU FOR YOUR CO-OPERATION AND TIME.

PATIENT DETAILS

Please write your name and contact details in CAPITAL LETTERS BELOW so that we may contact you by post for the questionnaire at 3 months or by post/email/phone if reminders are necessary.

Today's date: D D / M M / 2 0 Y Y

Title:

First name:

Surname:

Address:

Town/City:

County:

Postcode:

Phone: -

Mobile: -

E-mail:

Please answer ALL the questions below. Before answering each question, read through all the options and then tick the box or boxes that best describe(s) you.

A. The following questions are about you and your low back pain.

A1. Are you? ***(tick ONE)***

- ☐ Male
- ☐ Female

A2. How old are you? ***(in YEARS)***

☐☐

A3. Please describe your CURRENT WORK (PAID EMPLOYMENT) STATUS? *(tick ONE)*

- ☐ In paid employment
- ☐ At home and not looking for work
- ☐ Unemployed because of back pain
- ☐ Unemployed because of other reasons
- ☐ Retired
- ☐ Student

A4. How long is it since you had a WHOLE MONTH WITHOUT any back pain? *(tick ONE)*

- ☐ Less than 3 months
- ☐ 3-6 months
- ☐ 7-12 months
- ☐ 1-2 years
- ☐ 3-5 years
- ☐ 6-10 years
- ☐ More than 10 years

A5. Are you taking any MEDICATION (PAIN KILLERS) for your back pain? *(tick ONE)*

Every day	Sometimes	Rarely	Never
☐	☐	☐	☐

B. When your back hurts, you may find it difficult to do some of the things you normally do. This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you TODAY.

When you read a sentence that describes you TODAY, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you TODAY.

B1.	☐	I stay at home most of the time because of my back.
B2.	☐	I change position frequently to try and get my back comfortable.
B3.	☐	I walk more slowly than usual because of my back.
B4.	☐	Because of my back I am not doing any of the jobs that I usually do around the house.
B5.	☐	Because of my back, I use a handrail to get upstairs.
B6.	☐	Because of my back, I lie down to rest more often.
B7.	☐	Because of my back, I have to hold on to something to get out of an easy chair.
B8.	☐	Because of my back, I try to get other people to do things for me.
B9.	☐	I get dressed more slowly than usual because of my back.
B10.	☐	I only stand for short periods of time because of my back.
B11.	☐	Because of my back, I try not to bend or kneel down.
B12.	☐	I find it difficult to get out of a chair because of my back.
B13.	☐	My back is painful almost all the time.
B14.	☐	I find it difficult to turn over in bed because of my back.
B15.	☐	My appetite is not very good because of my back pain.
B16.	☐	I have trouble putting on my socks (or stockings) because of the pain in my back.
B17.	☐	I only walk short distances because of my back.
B18.	☐	I sleep less well because of my back.
B19.	☐	Because of my back pain, I get dressed with help from someone else.
B20.	☐	I sit down for most of the day because of my back.
B21.	☐	I avoid heavy jobs around the house because of my back.
B22.	☐	Because of my back pain, I am more irritable and bad tempered with people than usual.
B23.	☐	Because of my back, I go upstairs more slowly than usual.
B24.	☐	I stay in bed most of the time because of my back

C. By placing A TICK IN ONE BOX IN EACH GROUP BELOW, please indicate which statements best describe your own HEALTH STATE TODAY.

C1. Mobility

- I have NO problems walking about ☐
- I have SOME problems in walking about ☐
- I am CONFINED TO BED ☐

C2. Self-Care

- I have NO problems with self-care ☐
- I have SOME problems washing or dressing myself ☐
- I am UNABLE to wash or dress myself ☐

C3. Usual Activities
(e.g. work, study, housework, family or leisure activities)

- I have NO problems with performing my usual activities ☐
- I have SOME problems with performing my usual activities ☐
- I am UNABLE to perform my usual activities ☐

C4. Pain/Discomfort

- I have NO pain or discomfort ☐
- I have MODERATE pain or discomfort ☐
- I have EXTREME pain or discomfort ☐

C5. Anxiety/Depression

- I am NOT anxious or depressed ☐
- I am MODERATELY anxious or depressed ☐
- I am EXTREMELY anxious or depressed ☐

D. The following question is about your low back pain and how it has been IN THE PAST WEEK.

D1. In the past week, how BOTHERSOME has your back pain been? *(tick ONE)*

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

E. Please TICK ONE BOX FOR EACH OF THE FOLLOWING QUESTIONS about your low back pain and how it has affected you OVER THE PAST FEW DAYS.

E1. Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E2. Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E3. Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E4. Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/ concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E5. Over the past few days, how depressed (down-in-the–dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E6. Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10' is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it now worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E7. Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

THANK YOU FOR YOUR TIME IN COMPLETING THIS FORM.

PLEASE RETURN THIS QUESTIONNAIRE TO THE PERSON WHO GAVE IT TO YOU.

FOR CLINIC STAFF USE ONLY

If the patient did NOT consent to take part in the study, please complete the following about the patient:

Today's date:	D	D	M	M	2	0	Y	Y

Sex:	Male		Female	

Date of birth:	D	D	M	M	1	9	Y	Y

INFORMATION FOR CLINIC STAFF

After the patient has returned the questionnaire to you, please:

- ✓ Place the questionnaire into one of the pre-paid envelopes supplied and return it to the AECC as soon as possible.

PLEASE REMEMBER – only one questionnaire in a single envelope

CHIROPRACTIC

PATIENT-REPORTED OUTCOME MEASURES

Code number:					

QUESTIONNAIRE 2

AT THREE MONTHS

ANGLO-EUROPEAN
COLLEGE OF CHIROPRACTIC

British
Chiropractic
Association

INFORMATION

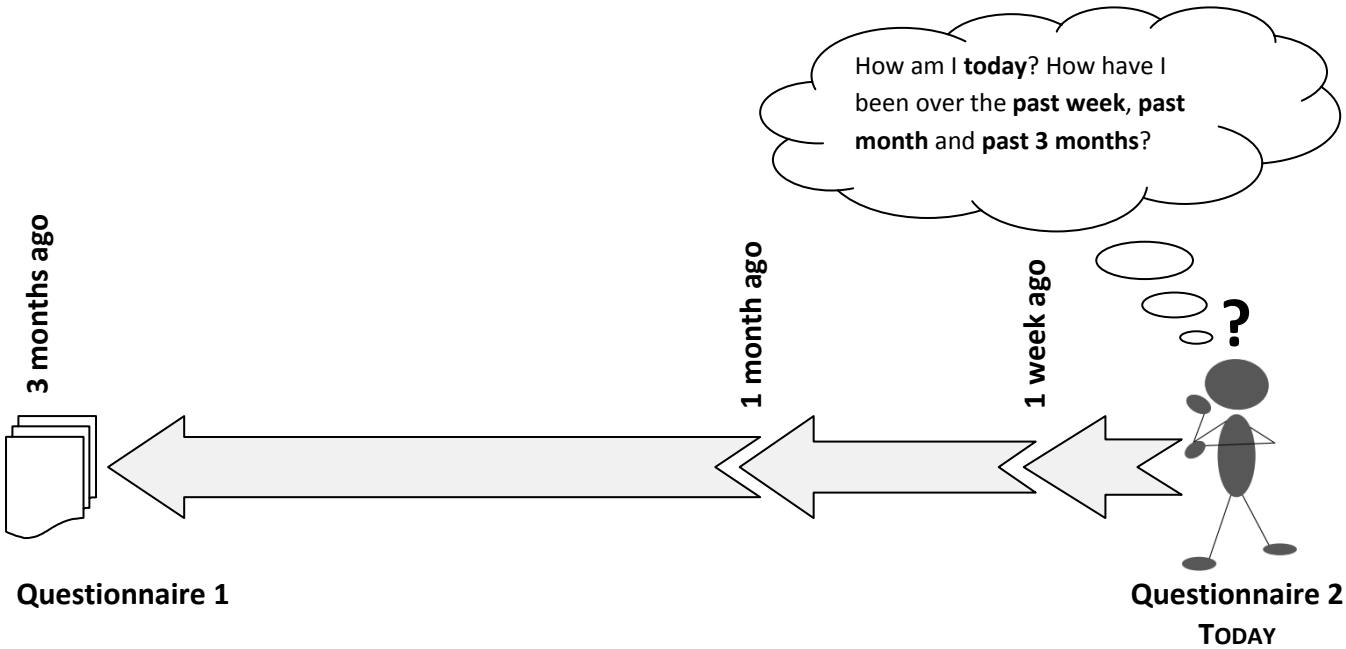
About three months ago, at the chiropractic clinic, you completed a questionnaire about your low back pain. As a follow up, we now ask you to complete this questionnaire and return it using the pre-paid envelope provided. Please state today's date and your name below. Your name is only required so we can match this questionnaire to the one you completed three months ago. None of the information you give here will be divulged to your chiropractor; it will only be used (anonymously) for the purpose of the research study.

Today's date:	D	D		M	M		2	0	Y	Y

Your name:																			

Questionnaire Instructions

The questions on the following pages are about your back pain and how it has been since you completed the first questionnaire. The form starts by asking you to consider how your back pain is **TODAY** and then how it has been over the **PAST WEEK, PAST MONTH AND PAST 3 MONTHS**. Please think back and try to remember how your back pain has changed during this period of time.



Want to know more?

Dr Taco Houweling (Principal Investigator): Tel: 01202 436234 / 079 31444501; Email: thouweling@aecc.ac.uk
Professor Jennifer Bolton (Study Supervisor): Tel: 01202 436200; Email: jbolton@aecc.ac.uk
Dr David Newell (Study Supervisor): Tel: 01202 436200; Email: dnewell@aecc.ac.uk

Anglo-European College of Chiropractic (AECC), 13-15 Parkwood Road, BOURNEMOUTH BH5 2DF.

THANK YOU FOR YOUR CO-OPERATION AND TIME.

A. When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you TODAY.

When you read a sentence that describes you TODAY, put a tick against it.
If the sentence does not describe you, then leave the space blank and go on to the next one.
Remember, only tick the sentence if you are sure it describes you TODAY.

A1.	☐	I stay at home most of the time because of my back.
A2.	☐	I change position frequently to try and get my back comfortable.
A3.	☐	I walk more slowly than usual because of my back.
A4.	☐	Because of my back I am not doing any of the jobs that I usually do around the house.
A5.	☐	Because of my back, I use a handrail to get upstairs.
A6.	☐	Because of my back, I lie down to rest more often.
A7.	☐	Because of my back, I have to hold on to something to get out of an easy chair.
A8.	☐	Because of my back, I try to get other people to do things for me.
A9.	☐	I get dressed more slowly than usual because of my back.
A10.	☐	I only stand for short periods of time because of my back.
A11.	☐	Because of my back, I try not to bend or kneel down.
A12.	☐	I find it difficult to get out of a chair because of my back.
A13.	☐	My back is painful almost all the time.
A14.	☐	I find it difficult to turn over in bed because of my back.
A15.	☐	My appetite is not very good because of my back pain.
A16.	☐	I have trouble putting on my socks (or stockings) because of the pain in my back.
A17.	☐	I only walk short distances because of my back.
A18.	☐	I sleep less well because of my back.
A19.	☐	Because of my back pain, I get dressed with help from someone else.
A20.	☐	I sit down for most of the day because of my back.
A21.	☐	I avoid heavy jobs around the house because of my back.
A22.	☐	Because of my back pain, I am more irritable and bad tempered with people than usual.
A23.	☐	Because of my back, I go upstairs more slowly than usual.
A24.	☐	I stay in bed most of the time because of my back

B. By placing A TICK IN ONE BOX IN EACH GROUP BELOW, please indicate which statements best describe your own HEALTH STATE TODAY.

B1. Mobility

I have NO problems walking about ☐

I have SOME problems in walking about ☐

I am CONFINED TO BED ☐

B2. Self-Care

I have NO problems with self-care ☐

I have SOME problems washing or dressing myself ☐

I am UNABLE to wash or dress myself ☐

B3. Usual Activities
(e.g. work, study, housework, family or leisure activities)

I have NO problems with performing my usual activities ☐

I have SOME problems with performing my usual activities ☐

I am UNABLE to perform my usual activities ☐

B4. Pain/Discomfort

I have NO pain or discomfort ☐

I have MODERATE pain or discomfort ☐

I have EXTREME pain or discomfort ☐

B5. Anxiety/Depression

I am NOT anxious or depressed ☐

I am MODERATELY anxious or depressed ☐

I am EXTREMELY anxious or depressed ☐

C. The following question is about your low back pain and how it has been IN THE PAST WEEK.

C1. In the past week, how BOTHERSOME has your back pain been? *(tick ONE)*

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

D. Please TICK ONE BOX FOR EACH OF THE FOLLOWING QUESTIONS about your low back pain and how it has affected you OVER THE PAST FEW DAYS.

D1. Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D2. Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D3. Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D4. Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/ concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D5. Over the past few days, how depressed (down-in-the–dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D6. Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10' is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it now worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D7. Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E. The following questions are about your low back pain and how it has affected you IN THE PAST MONTH.

E1. Have you been FREE OF YOUR BACK PAIN for the past month? ***(tick ONE)***

☐ No

☐ Yes → ***If yes, how long ago did this pain-free period first start? (in WEEKS)*** ☐☐

E2. For the past month, have you been able to carry on (or resume) YOUR USUAL WORK/ ACTIVITIES/TASKS (e.g. work, washing and dressing, housework, walking, sitting, exercise) without any interference from back pain? ***(tick ONE)***

☐ No

☐ Yes → ***If yes, how long ago did your back pain first cause no interference? (in WEEKS)*** ☐☐

E3. For the past month, have you had AN ACCEPTABLE QUALITY OF LIFE (e.g. socialising with family and friends, sleeping well, feeling well, energetic and confident) without any interference from back pain? ***(tick ONE)***

☐ No

☐ Yes → ***If yes, how long ago did your back pain first cause no interference? (in WEEKS)*** ☐☐

F. The following questions are about your low back pain and how it has been IN THE PAST 3 MONTHS (SINCE YOU COMPLETED THE FIRST QUESTIONNAIRE).

F1. In the past 3 months, have you needed to take any TIME OFF WORK (PAID EMPLOYMENT) for your back pain? ***(tick ONE)***

☐ No

☐ Yes → ***If yes, please state for how long you were/have been off work? (in DAYS)*** ☐☐

☐ I am not in paid employment
(e.g. at home and not looking for work, retired, student, unemployed)

F2. In the past 3 months, how has your use of MEDICATION (PAIN KILLERS) for your back pain changed? (*tick ONE*)

- ☐ I have NEVER, or HARDLY EVER, used any pain killers
- ☐ I have REDUCED my use of pain killers
- ☐ I am taking about the SAME amount of pain killers
- ☐ I have INCREASED my use of pain killers

F3. In the past 3 months, did you receive ANY of the following for your back pain? *(tick AS MANY AS APPLY)*

- ☐ X-Ray
- ☐ MRI/CT scan
- ☐ Injections into spine (e.g. epidural)
- ☐ Low back surgery

F4. In the past 3 months, have you applied for/received DISABILITY/INCAPACITY BENEFITS for your back pain? *(tick ONE)*

- ☐ Yes
- ☐ No

Please go to F5.

F5. In the past 3 months, did you attend ANY of the following for your back pain? *(tick AS MANY AS APPLY)*

- ☐ GP
- ☐ Outpatient hospital visit to Accident and Emergency department
- ☐ Outpatient hospital visit to a physiotherapist
- ☐ Outpatient hospital visit to a medical specialist (e.g. pain clinic, orthopaedic surgery, rheumatology)
- ☐ Overnight stay in hospital

F6. How would you describe your back pain NOW compared to how you were 3 months ago when you completed the first questionnaire? *(tick ONE)*

- ☐ Very much improved
- ☐ Much improved
- ☐ Slightly improved
- ☐ No change
- ☐ Slightly worsened
- ☐ Much worsened
- ☐ Very much worsened

F7. Please indicate whether you have made any CHANGES in the following in order to TAKE CARE OF YOUR BACK in the past 3 months? *(tick ONE BOX PER LINE)*

	Increased	No change	Decreased
Awareness of early warning signs of back pain	☐	☐	☐
Rest	☐	☐	☐
Specific exercises for your back	☐	☐	☐
General physical activity/exercise	☐	☐	☐
Care when lifting	☐	☐	☐
Awareness of posture	☐	☐	☐

G. The following questions are about chiropractic treatment for your low back pain IN THE PAST 3 MONTHS (SINCE YOU COMPLETED THE FIRST QUESTIONNAIRE).

G1. In the past 3 months, HOW MANY chiropractic treatment sessions have you received for your back pain? ***(please write in NUMBER OF SESSIONS)***

G2. When was your LAST chiropractic treatment session? ***(tick ONE)***

1 month ago or less	Between 1 and 2 months ago	More than 2 months ago
☐	☐	☐

G3. Did you experience any worsening of your back pain, stiffness, soreness and/or general discomfort IMMEDIATELY OR SHORTLY AFTER any of these chiropractic treatment sessions? ***(tick ONE)***

- ☐ No
- ☐ Unsure
- ☐ Yes, but I could carry on with my usual activities and/or work
- ☐ Yes and I could NOT carry on with my usual activities and/or work

G4. Overall, how SATISFIED are you with the chiropractic care you received for your back pain? ***(tick ONE)***

Very satisfied	Satisfied	Undecided	Dissatisfied	Very dissatisfied
☐	☐	☐	☐	☐

G5. Overall, how do you feel the chiropractic care helped your back pain? ***(tick ONE)***

Very helpful	Helpful	Undecided	Unhelpful	Very Unhelpful
☐	☐	☐	☐	☐

H. Finally, we would like some FEEDBACK regarding the QUESTIONNAIRES you have completed for this study (tick ONE BOX FOR EACH STATEMENT).

	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
H1. Overall, the questions were clear and easy to answer	☐	☐	☐	☐	☐
H2. Overall, the questions were relevant to me and my back pain	☐	☐	☐	☐	☐
H3. Overall, completion of the questionnaires was NOT too disruptive or time consuming	☐	☐	☐	☐	☐

THANK YOU FOR YOUR TIME IN COMPLETING THIS FORM.
PLEASE RETURN THIS QUESTIONNAIRE IN THE PRE-PAID ENVELOPE.

22 November 2010

Dear ...,

RE: Chiropractic Patient-Reported Outcome Measures Study (C-PROMS)

Thank you for agreeing to participate in the above study.

Please find enclosed the following documents:

- ✓ 1 User guide
- ✓ 10 Pre-treatment questionnaires (Questionnaire 1)
- ✓ 10 Pre-paid return envelopes

The first thing you should do is carefully read about the study and how it is conducted in the User Guide. This should take you no more than 5-10 minutes. The study has been designed to cause minimal disruption to your practice. The data collection process is straightforward, but it is important that you understand the procedures we ask you to follow. If you have any questions, please feel free to contact us, either by phone or email, using the contact details given on page 3 of the User Guide. Moreover, if you require additional questionnaires or pre-paid envelopes please do not hesitate to contact the Principal Investigator.

Once you are familiar with the procedures of the study, you are ready to start. You can start at any time that is convenient to you, but once you do start you must **consecutively** recruit 10 patients who meet the eligibility criteria. It is important that you follow the instructions detailed in the User Guide so that all the data you collect are valid and complete. The credibility of this study is dependent on your efforts and diligence in this process, and for this we are very grateful.

All participating chiropractors will automatically be entered into a prize draw unless we hear from you to the contrary. The results of the draw will be announced near the end of the study.

Thank you for your time.

Yours sincerely,

Taco Houweling, DC, MRes (Principal Investigator)
Tel: 01202 436234 / 079 31444501
Email: thouweling@aecc.ac.uk

Jennifer Bolton, PhD, MA (Ed.), FCC (Hon)

David Newell, MSc, PhD

21 September 2010

Dear Sir/Madam,

RE: Chiropractic Patient-Reported Outcome Measures Study (C-PROMS)

Thank you for agreeing to participate in the above study.

Please find enclosed the following documents:

- ✓ Questionnaire
- ✓ Pre-paid return envelope

About three months ago you completed a questionnaire about your low back pain at the chiropractic clinic. We now ask you to complete a final follow-up questionnaire for this study. The information you provide in this questionnaire will help us improve patient care, from which you may benefit.

The first thing you should do is read the information and instructions on page 2 of the enclosed questionnaire. Once you have done so, you are ready to complete the questionnaire, which should take you no more than 5-10 minutes of your time. Please do so and return it as soon as possible in the pre-paid envelope provided. For your convenience, this questionnaire can also be completed and submitted online at http://www.aecc.ac.uk/research/c-proms.aspx using the code number on the front cover of the enclosed questionnaire.

Thank you for your co-operation and time.

Yours faithfully,

Taco Houweling (Principal Investigator)
Tel: 01202 436234 / 079 31444501
Email: thouweling@aecc.ac.uk

Jennifer Bolton (Study Supervisor)

David Newell (Study Supervisor)

Please state below the TOTAL NUMBER OF TREATMENTS each patient received during the study period from the FIRST DAY THEY ATTENDED THE CLINIC (initial consultation) to the END OF THE STUDY PERIOD (INCLUSIVE).

Patient name	Study period ends:	Total number of visits during study period (includes initial consultation visit)
1. asdf	adsf	
2. asdf	asdf	
3. asdf	asdf	
4. asdf	asdf	
5. asdf	asdf	

1 July 2011

Dear ...,

RE: Chiropractic Patient-Reported Outcome Measure Study (C-PROMS); Number of visits to the clinic

A few months ago, you participated in this study by administering questionnaires to a number of NEW low back pain patients presenting to your clinic; thank you for doing so. We now need to ask you the total number of treatments these new patients received during the study period. This information can be gathered from your computer booking software.

Please fill in the enclosed form and return it in the pre-paid envelope provided as soon as possible. These data will be kept completely confidential. Please find enclosed a copy of the signed informed consent forms of the participating patients to allow you to release this information.

Thank you very much for your time and co-operation.

Kind Regards,

Taco Houweling (Principal Investigator)
Tel: 01202 436234 / 079 31444501
Email: thouweling@aecc.ac.uk

Jennifer Bolton (Study Supervisor)

David Newell (Study Supervisor)

Appendix 2: Main study documentation.

- User guide regarding data collection process
- Baseline and follow-up questionnaire
- Cover letter accompanying data collection pack –
  for the attention of chiropractors and clinic staff
- Cover letter accompanying follow-up questionnaire –
  for the attention of participants
- Number of patient visits form and accompanying cover letter –
  for the attention of chiropractors and clinic staff

USER GUIDE

1. What is this study about?

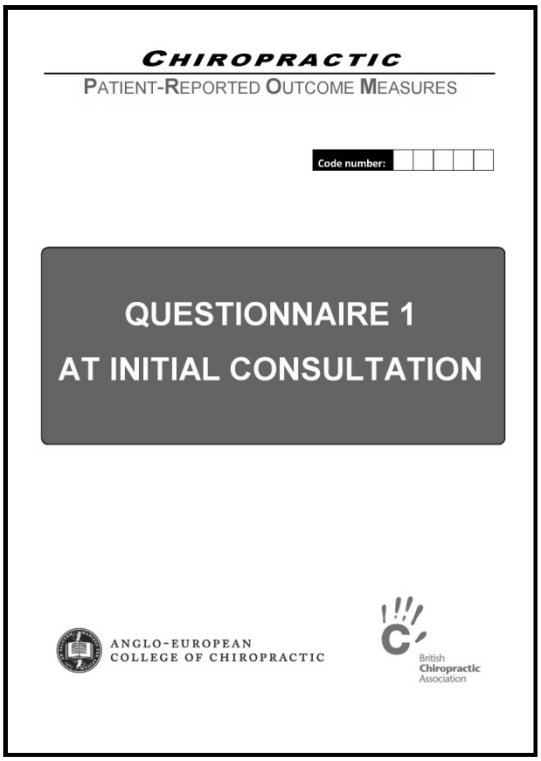
The purpose of the **C**hiropractic **P**atient **R**eported **O**utcome **M**easures **S**tudy (**C-PROMS**) is to develop two short questionnaires to collect routine information concerning outcomes and costs in chiropractic practices across the United Kingdom**.** This information is required to assess and improve the quality of chiropractic care and to inform patients, clinicians and third-party payers.

2. How is the study being done?

You or your staff will collect data (Questionnaire 1) from **10 consecutive eligible new patients** presenting to your clinic for the **first time** with **low back pain**. These patients can be seen by **any** chiropractor working in your clinic. Thereafter, patients will be sent a second questionnaire (Questionnaire 2) at three months by post from the AECC, so there is no work involved for your clinic. If your clinic is equipped with a computer booking system, you or your staff **may** be sent a form requesting the total number of visits each of these patients made to the clinic within this three month period. For administrative purposes, if you work in multiple clinics, this study should be conducted in **one clinic only**. All your contact details will be kept confidential for the purposes of this study.

3. When does the study start?

The study starts in August 2010.



4. Setting up the study

Before data collection can start, the following should have happened:

- You should have received copies of Questionnaire 1 and a pre-paid return envelope for each copy.
- You should have read this User Guide and if you have staff (e.g. receptionist, practice manager) ensure all of them understand how to collect and submit data (they all should have read this User Guide).

NOW YOU ARE READY TO START DATA COLLECTION.

5. Patient eligibility criteria for participation in the study

To be eligible for participation in the study, patients must fulfil ALL of the following:

- ✓ Patients must **HAVE LOW BACK PAIN WITH OR WITHOUT LEG PAIN** as their main complaint
- ✓ Patients must be **18 years of age or older**
- ✓ Patients must **NOT HAVE** received treatment for their low back pain from a healthcare professional **EXCEPT FROM THEIR GP** in the **PAST 3 MONTHS**
- ✓ Patients must **NOT be pregnant**
- ✓ Patients must be **literate in English**

6. Patient recruitment

a. On the phone

You will recruit **10 CONSECUTIVE NEW PATIENTS** presenting with **low back pain**. When these new patients make an appointment at the clinic they should be told:

- "the clinic is currently taking part in a study about low back pain"
- "you will be given more information about the study when you arrive for your appointment so you can decide whether you want to take part or not"
- "there will be no change to your chiropractic treatment whether you want to take part or not"
- "we would like you to arrive 5-10 minutes early for your appointment to allow time for you to read the information about the study and complete the forms"

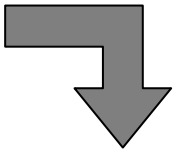
b. At the clinic

Please consider the following questions:

- **Is the patient eligible (refer to eligibility criteria) to enter the study?**

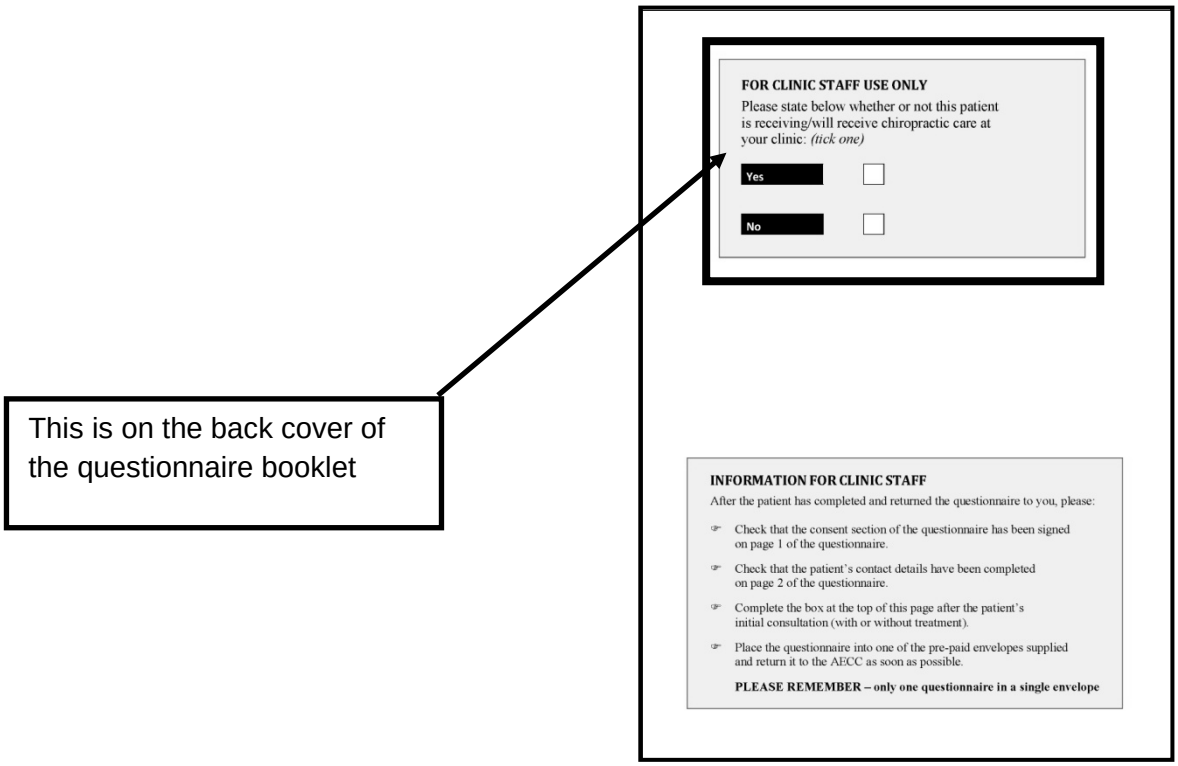
If they are **not eligible**, take no further action.

If they are **eligible**, then proceed to the next stage.



- **If eligible, then** please give them the questionnaire booklet (Questionnaire 1) and ask them to read the information at the start (page 1) and decide if they wish to complete the questionnaire. The questionnaire has been designed for patients to read and complete by themselves; you do not have to help the patient with the questionnaire. The patient now reads the information at the start of the Questionnaire (page 1).

- **If after reading the information the patient informs you that they DO NOT want to take part**, please ask the patient to return the questionnaire to you and take no further action.
- **If a patient decides they DO want to take part in the study, please ask them to proceed and complete the questionnaire. The patient must complete the questionnaire in the practice before any treatment and return it to you straight away. Then, please:**
    - ✓ Check that the patient has signed the informed consent on page 1 and the patient's contact details have been completed on page 2 of the questionnaire.
    - ✓ After the initial consultation (with or without treatment), complete the box on the back cover of the questionnaire (see diagram below). This can be done by clinic staff when the patient returns to the front desk for payment and/or further appointment booking.



- ✓ Place the completed questionnaire into one of the pre-paid envelopes supplied and return it to the Principal Investigator at the AECC (one questionnaire in a single envelope) as soon as possible. You do NOT have to wait until all the data are collected (10 patients) to return each questionnaire.

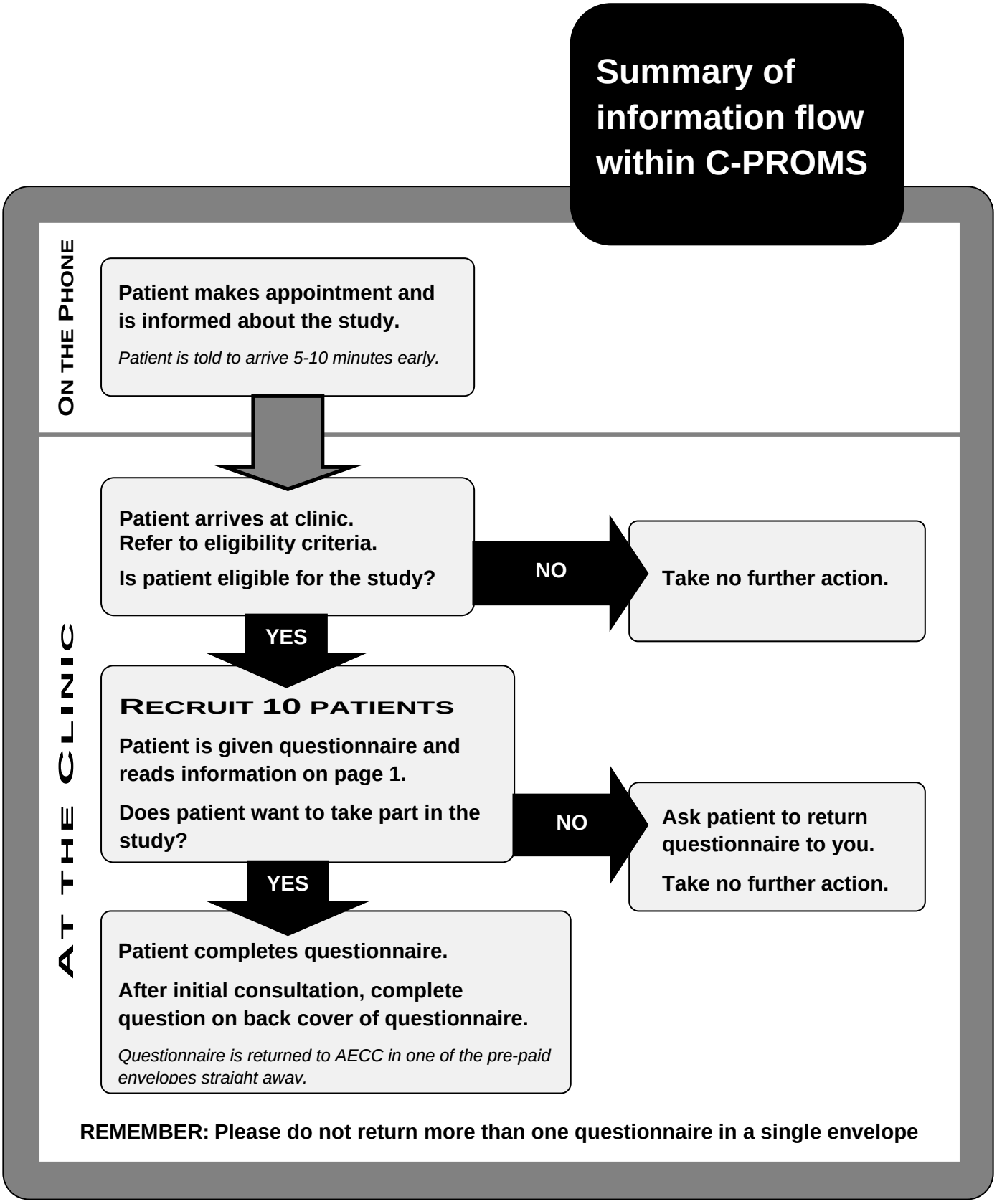
7. Want to know more?

Mr Taco Houweling (Principal Investigator): Tel: 01202 436234 / 079 31444501; Email: thouweling@aecc.ac.uk

Professor Jennifer Bolton (Study Supervisor): Tel: 01202 436200; Email: jbolton@aecc.ac.uk

Dr David Newell (Study Supervisor): Tel: 01202 436200; Email: dnewell@aecc.ac.uk

Anglo-European College of Chiropractic (AECC), 13-15 Parkwood Road, BOURNEMOUTH BH5 2DF.



Acknowledgments: C-PROMS is funded by the British Chiropractic Association (BCA) and the Anglo-European College of Chiropractic (AECC). The study has been submitted and approved by the Ethics Sub-Committee of the AECC.

THANK YOU FOR YOUR TIME AND HELP WITH THIS STUDY.

CHIROPRACTIC

PATIENT-REPORTED OUTCOME MEASURES

Code number:					

QUESTIONNAIRE 1
AT INITIAL CONSULTATION

ANGLO-EUROPEAN
COLLEGE OF CHIROPRACTIC

British
Chiropractic
Association

INFORMATION AND YOUR CONSENT

What is the Chiropractic Patient-Reported Outcome Measures Study (C-PROMS)?

The purpose of this research study is to collect information in chiropractic clinics regarding your experiences of care and the costs of treatment. The information that patients provide is an important part of the way in which decisions are made regarding the delivery of healthcare services in the UK.

How is the study being done?

You will be asked to complete two questionnaires; each one will take about 5-10 minutes of your time. The first questionnaire you will be asked to complete today. The second questionnaire you will receive in the post in about 3 months time, which you will be asked to complete and then return in an enclosed stamped addressed envelope. In addition, we may ask your chiropractor the total number of visits you have made to the clinic over this 3-month period.

Who is undertaking this study?

Mr Taco Houweling is the Principal Investigator, and is conducting this study as part of a PhD funded by the Anglo-European College of Chiropractic and the British Chiropractic Association.

Why should I take part?

This study will help improve patient care in the future, from which you may benefit.

Do I have to take part?

Your participation is voluntary and you are free to withdraw at any time without giving any reason. Your chiropractic care is NOT affected either by your decision to participate or not, or by any decision to withdraw once you have started.

What will happen to the information I give?

All the information is strictly confidential and will NOT be divulged to your chiropractor. It will be used anonymously and only for the research study. Published reports will not refer to any individuals; your name and address are only required to enable us to send you the questionnaire at the 3-month follow-up. If we need to send you a reminder, we will do so by post, phone and/or email.

What now?

If you agree to take part please sign below and complete the questionnaire now. Otherwise, please hand back the questionnaire to the person who gave it to you.

I have read and understood the information given above and agree to take part in the study:

Signature:	Name (please print):	Date:

Want to know more?

Mr Taco Houweling (Principal Investigator): Tel: 07931444501; email: thouweling@aecc.ac.uk
Professor Jennifer Bolton (Study Supervisor): Tel: 01202 436200; email: jbolton@aecc.ac.uk
Dr David Newell (Study Supervisor): Tel: 01202 436200; email: dnewell@aecc.ac.uk

Anglo-European College of Chiropractic (AECC), 13-15 Parkwood Road, BOURNEMOUTH BH5 2DF.

THANK YOU FOR YOUR CO-OPERATION AND TIME.

PATIENT DETAILS

Please write your name and contact details in CAPITAL LETTERS BELOW so that we may contact you by post for the questionnaire at 3 months or by post/email/phone if reminders are necessary.

Today's date: D D / M M / 2 0 Y Y

Title:

First name:

Surname:

Address:

Town/City:

County:

Postcode:

Phone: -

Mobile: -

E-mail:

Please answer ALL the questions below. Before answering each question, read through all the options and then tick the box or boxes that best describe(s) you.

A. The following questions are about you and your low back pain.

A1. Are you? ***(tick ONE)***

- ☐ Male
- ☐ Female

A2. How old are you? ***(in YEARS)***

☐☐

A3. Please describe your CURRENT WORK (PAID EMPLOYMENT) STATUS? *(tick ONE)*

- ☐ In paid (including self) employment
- ☐ At home and not looking for work
- ☐ Unemployed because of back pain
- ☐ Unemployed because of other reasons
- ☐ Retired
- ☐ Student

A4. How long is it since you had a WHOLE MONTH WITHOUT any back pain? *(tick ONE)*

- ☐ Less than 3 months
- ☐ 3-6 months
- ☐ 7-12 months
- ☐ 1-2 years
- ☐ 3-5 years
- ☐ 6-10 years
- ☐ More than 10 years

A5. Are you taking any MEDICATION (PAIN KILLERS) for your back pain? *(tick ONE)*

Never	Rarely	Sometimes	Every day
☐	☐	☐	☐

B. When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you TODAY.

When you read a sentence that describes you TODAY, put a tick against it.
If the sentence does not describe you, then leave the space blank and go on to the next one.
Remember, only tick the sentence if you are sure it describes you TODAY.

B1.	☐	I stay at home most of the time because of my back.
B2.	☐	I change position frequently to try and get my back comfortable.
B3.	☐	I walk more slowly than usual because of my back.
B4.	☐	Because of my back I am not doing any of the jobs that I usually do around the house.
B5.	☐	Because of my back, I use a handrail to get upstairs.
B6.	☐	Because of my back, I lie down to rest more often.
B7.	☐	Because of my back, I have to hold on to something to get out of an easy chair.
B8.	☐	Because of my back, I try to get other people to do things for me.
B9.	☐	I get dressed more slowly than usual because of my back.
B10.	☐	I only stand for short periods of time because of my back.
B11.	☐	Because of my back, I try not to bend or kneel down.
B12.	☐	I find it difficult to get out of a chair because of my back.
B13.	☐	My back is painful almost all the time.
B14.	☐	I find it difficult to turn over in bed because of my back.
B15.	☐	My appetite is not very good because of my back pain.
B16.	☐	I have trouble putting on my socks (or stockings) because of the pain in my back.
B17.	☐	I only walk short distances because of my back.
B18.	☐	I sleep less well because of my back.
B19.	☐	Because of my back pain, I get dressed with help from someone else.
B20.	☐	I sit down for most of the day because of my back.
B21.	☐	I avoid heavy jobs around the house because of my back.
B22.	☐	Because of my back pain, I am more irritable and bad tempered with people than usual.
B23.	☐	Because of my back, I go upstairs more slowly than usual.
B24.	☐	I stay in bed most of the time because of my back

C. By placing A TICK IN ONE BOX IN EACH GROUP BELOW, please indicate which statements best describe your own HEALTH STATE TODAY.

C1. Mobility

- I have NO problems in walking about ☐
- I have SOME problems in walking about ☐
- I am CONFINED TO BED ☐

C2. Self-Care

- I have NO problems with self-care ☐
- I have SOME problems washing or dressing myself ☐
- I am UNABLE to wash or dress myself ☐

C3. Usual Activities
(e.g. work, study, housework, family or leisure activities)

- I have NO problems with performing my usual activities ☐
- I have SOME problems with performing my usual activities ☐
- I am UNABLE to perform my usual activities ☐

C4. Pain/Discomfort

- I have NO pain or discomfort ☐
- I have MODERATE pain or discomfort ☐
- I have EXTREME pain or discomfort ☐

C5. Anxiety/Depression

- I am NOT anxious or depressed ☐
- I am MODERATELY anxious or depressed ☐
- I am EXTREMELY anxious or depressed ☐

D. The following question is about your low back pain and how it has been IN THE PAST WEEK.

D1. In the past week, how BOTHERSOME has your back pain been? *(tick ONE)*

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

E. Please TICK ONE BOX FOR EACH OF THE FOLLOWING QUESTIONS about your low back pain and how it has affected you OVER THE PAST FEW DAYS.

E1. Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E2. Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E3. Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E4. Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/ concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E5. Over the past few days, how depressed (down-in-the–dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E6. Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10' is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it no worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E7. Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

THANK YOU FOR YOUR TIME IN COMPLETING THIS FORM.

PLEASE RETURN THIS QUESTIONNAIRE TO THE PERSON WHO GAVE IT TO YOU.

FOR CLINIC STAFF USE ONLY

Please state below whether or not this patient is receiving/will receive chiropractic care at your clinic: *(tick one)*

Yes ☐

No ☐

INFORMATION FOR CLINIC STAFF

After the patient has completed and returned the questionnaire to you, please:

- ☞ Check that the consent section of the questionnaire has been signed on page 1 of the questionnaire.
- ☞ Check that the patient's contact details have been completed on page 2 of the questionnaire.
- ☞ Complete the box at the top of this page after the patient's initial consultation (with or without treatment).
- ☞ Place the questionnaire into one of the pre-paid envelopes supplied and return it to the AECC as soon as possible.

PLEASE REMEMBER – only one questionnaire in a single envelope

CHIROPRACTIC

PATIENT-REPORTED OUTCOME MEASURES

If you would prefer to complete this questionnaire ONLINE, please go to:
http://www.aecc.ac.uk/research/c-proms.aspx

Code number:	B				

QUESTIONNAIRE 2

AT FOLLOW-UP

ANGLO-EUROPEAN
COLLEGE OF CHIROPRACTIC

British
Chiropractic
Association

INFORMATION

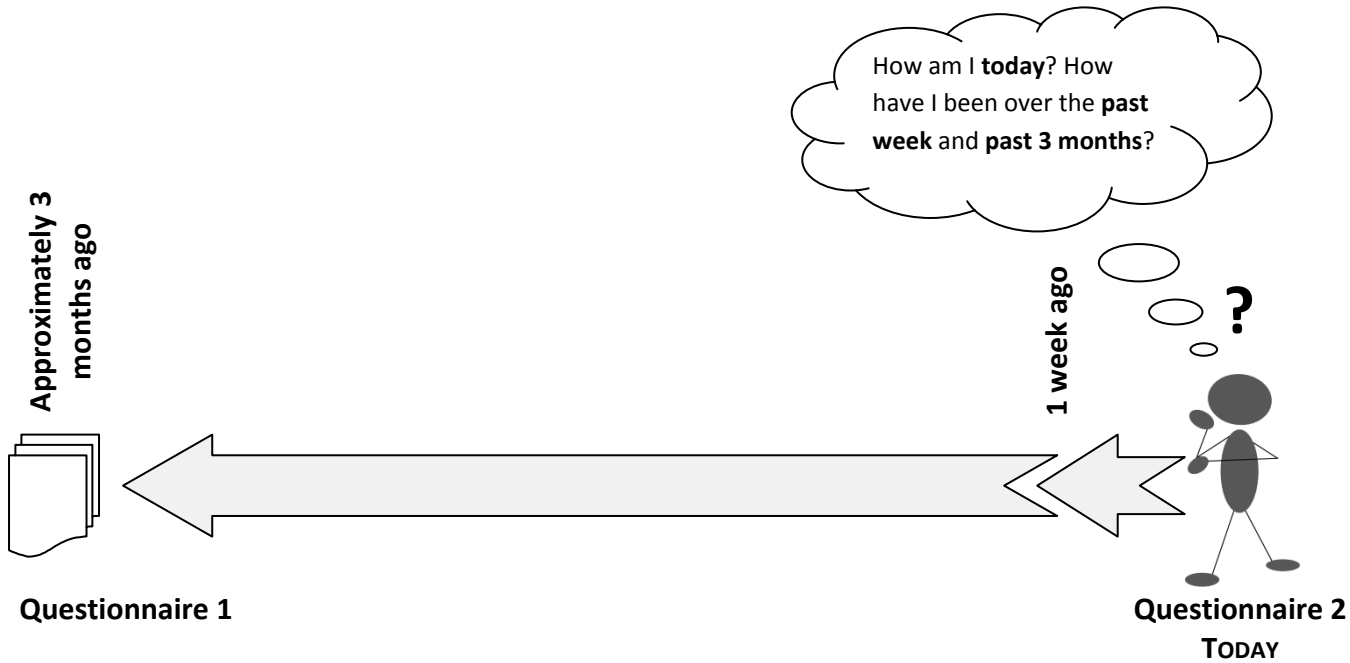
About three months ago, at the chiropractic clinic, you completed a questionnaire about your low back pain. As a follow up, we now ask you to complete this questionnaire and return it using the pre-paid envelope provided. Please state today's date and your name below. Your name is only required so we can match this questionnaire to the one you completed three months ago. None of the information you give here will be divulged to your chiropractor; it will only be used (anonymously) for the purpose of the research study.

Today's date:	D	D		M	M		2	0	Y	Y

Your name:																			

Questionnaire Instructions

The questions on the following pages are about your back pain and how it has been since you completed the first questionnaire, which in most cases will be about 3 months ago. The form starts by asking you to consider how your back pain is **TODAY** and then how it has been over the **PAST WEEK AND PAST 3 MONTHS**. Please think back and try to remember how your back pain has changed during this period of time.



Want to know more?

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Anglo-European College of Chiropractic (AECC), 13-15 Parkwood Road, BOURNEMOUTH BH5 2DF.

THANK YOU FOR YOUR CO-OPERATION AND TIME.

A. When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you TODAY.

When you read a sentence that describes you TODAY, put a tick against it.
If the sentence does not describe you, then leave the space blank and go on to the next one.
Remember, only tick the sentence if you are sure it describes you TODAY.

A1.	☐	I stay at home most of the time because of my back.
A2.	☐	I change position frequently to try and get my back comfortable.
A3.	☐	I walk more slowly than usual because of my back.
A4.	☐	Because of my back, I am not doing any of the jobs that I usually do around the house.
A5.	☐	Because of my back, I use a handrail to get upstairs.
A6.	☐	Because of my back, I lie down to rest more often.
A7.	☐	Because of my back, I have to hold on to something to get out of an easy chair.
A8.	☐	Because of my back, I try to get other people to do things for me.
A9.	☐	I get dressed more slowly than usual because of my back.
A10.	☐	I only stand for short periods of time because of my back.
A11.	☐	Because of my back, I try not to bend or kneel down.
A12.	☐	I find it difficult to get out of a chair because of my back.
A13.	☐	My back is painful almost all the time.
A14.	☐	I find it difficult to turn over in bed because of my back.
A15.	☐	My appetite is not very good because of my back pain.
A16.	☐	I have trouble putting on my socks (or stockings) because of the pain in my back.
A17.	☐	I only walk short distances because of my back.
A18.	☐	I sleep less well because of my back.
A19.	☐	Because of my back pain, I get dressed with help from someone else.
A20.	☐	I sit down for most of the day because of my back.
A21.	☐	I avoid heavy jobs around the house because of my back.
A22.	☐	Because of my back pain, I am more irritable and bad tempered with people than usual.
A23.	☐	Because of my back, I go upstairs more slowly than usual.
A24.	☐	I stay in bed most of the time because of my back.

B. By placing A TICK IN ONE BOX IN EACH GROUP BELOW, please indicate which statements best describe your own HEALTH STATE TODAY.

B1. Mobility

I have NO problems in walking about ☐

I have SOME problems in walking about ☐

I am CONFINED TO BED ☐

B2. Self-Care

I have NO problems with self-care ☐

I have SOME problems washing or dressing myself ☐

I am UNABLE to wash or dress myself ☐

B3. Usual Activities
(e.g. work, study, housework, family or leisure activities)

I have NO problems with performing my usual activities ☐

I have SOME problems with performing my usual activities ☐

I am UNABLE to perform my usual activities ☐

B4. Pain/Discomfort

I have NO pain or discomfort ☐

I have MODERATE pain or discomfort ☐

I have EXTREME pain or discomfort ☐

B5. Anxiety/Depression

I am NOT anxious or depressed ☐

I am MODERATELY anxious or depressed ☐

I am EXTREMELY anxious or depressed ☐

C. The following question is about your low back pain and how it has been IN THE PAST WEEK.

C1. In the past week, how BOTHERSOME has your back pain been? *(tick ONE)*

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐

D. Please TICK ONE BOX FOR EACH OF THE FOLLOWING QUESTIONS about your low back pain and how it has affected you OVER THE PAST FEW DAYS.

D1. Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D2. Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D3. Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D4. Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/ concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D5. Over the past few days, how depressed (down-in-the–dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D6. Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10' is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it no worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

D7. Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E. The following questions are about your low back pain and how it has been IN THE PAST 3 MONTHS OR SO (SINCE YOU COMPLETED THE FIRST QUESTIONNAIRE).

E1. Since completing the first questionnaire, have you at any time had A WHOLE MONTH free of YOUR BACK PAIN? *(tick ONE)*

☐ No

☐ Yes → ***If yes, are you still in this pain-free period today? (tick one)*** ☐ No ☐ Yes

E2. Since completing the first questionnaire, have you at any time been able to carry out YOUR USUAL ACTIVITIES (e.g. work; washing and dressing; housework; walking; sitting; exercise) without interference from your back pain AND this interference-free period lasted A WHOLE MONTH? *(tick ONE)*

☐ No

☐ Yes → ***If yes, are you still in this interference-free period today? (tick one)*** ☐ No ☐ Yes

E3. Since completing the first questionnaire, have you at any time achieved an ACCEPTABLE QUALITY OF LIFE (e.g. socialising with family and friends; sleeping well; feeling well, energetic and confident) without interference from your back pain AND this interference-free period lasted A WHOLE MONTH? *(tick ONE)*

☐ No

☐ Yes → ***If yes, are you still in this interference-free period today? (tick one)*** ☐ No ☐ Yes

E4. Since completing the first questionnaire, have you needed to take any TIME OFF WORK (PAID EMPLOYMENT) for your back pain? *(tick ONE)*

☐ No

☐ Yes → ***If yes, please state for how long you were/have been off work? (in DAYS)*** ☐☐

☐ I am not in paid employment
(e.g. at home and not looking for work, retired, student, unemployed)

E5. Since completing the first questionnaire, how has your use of MEDICATION (pain killers) for your back pain changed? (*tick ONE*)

- ☐ I have NEVER, or HARDLY EVER, used any pain killers
- ☐ I have REDUCED my use of pain killers
- ☐ I am taking about the SAME amount of pain killers
- ☐ I have INCREASED my use of pain killers

E6. Since completing the first questionnaire, did you receive ANY of the following for your back pain? *(tick AS MANY AS APPLY)*

- ☐ X-Ray
- ☐ MRI/CT scan
- ☐ Injections into spine (e.g. epidural)
- ☐ Low back surgery

E7. Since completing the first questionnaire, have you applied for DISABILITY/INCAPACITY BENEFITS for your back pain? *(tick ONE)*

- ☐ No
- ☐ Yes

Please go to F5.

E8. Since completing the first questionnaire, did you attend ANY of the following for your back pain? *(tick AS MANY AS APPLY)*

- ☐ GP
- ☐ Outpatient hospital visit to Accident and Emergency department
- ☐ Outpatient hospital visit to a physiotherapist
- ☐ Outpatient hospital visit to a medical specialist (e.g. pain clinic, orthopaedic surgery, rheumatology)
- ☐ Overnight stay in hospital

E9. How would you describe your back pain NOW compared to how you were about 3 months ago when you completed the first questionnaire? *(tick ONE)*

- ☐ Completely recovered
- ☐ Much improved
- ☐ Slightly improved
- ☐ No change
- ☐ Slightly worsened
- ☐ Much worsened
- ☐ Worse than ever

E10. Please indicate whether you have made any CHANGES in the following in order to TAKE CARE OF YOUR BACK since you completed the first questionnaire? *(tick ONE BOX PER LINE)*

	Increased	No change	Decreased
Awareness of early warning signs of back pain	☐	☐	☐
Rest	☐	☐	☐
Specific exercises for your back	☐	☐	☐
General physical activity/exercise	☐	☐	☐
Care when lifting	☐	☐	☐
Awareness of posture	☐	☐	☐

F. The following questions are about chiropractic care for your low back pain IN THE PAST 3 MONTHS OR SO (SINCE YOU COMPLETED THE FIRST QUESTIONNAIRE).

F1. Since you completed the first questionnaire, HOW MANY visits have you made to the chiropractic clinic for your back pain (including your first visit)? ***(please write in NUMBER OF VISITS)***

F2. Did you experience any worsening of your back pain, stiffness, soreness and/or general discomfort IMMEDIATELY OR SHORTLY AFTER any of these chiropractic treatment visits? ***(tick ONE)***

- ☐ No
- ☐ Don't know
- ☐ Yes, but I could carry on with my usual activities and/or work
- ☐ Yes and I could NOT carry on with my usual activities and/or work

F3. Overall, how do you feel this chiropractic care helped your back pain? ***(tick ONE)***

Very helpful	Helpful	Don't know	Unhelpful	Very Unhelpful
☐	☐	☐	☐	☐

F4. Overall, how was the chiropractor at each of the following? ***(tick ONE)***

	Very good	Good	Don't know	Poor	Very poor
Giving you enough time	☐	☐	☐	☐	☐
Giving you an explanation for your back pain	☐	☐	☐	☐	☐
Involving you in decisions about your care	☐	☐	☐	☐	☐

G. Finally, we would like some FEEDBACK regarding the QUESTIONNAIRES you have completed for this study (tick ONE BOX FOR EACH STATEMENT).

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
Overall, the questions were clear and easy to answer	☐	☐	☐	☐	☐
Overall, the questions were relevant to me and my back pain	☐	☐	☐	☐	☐
Overall, completion of the questionnaires was NOT too disruptive or time consuming	☐	☐	☐	☐	☐

THANK YOU FOR YOUR TIME IN COMPLETING THIS FORM.
PLEASE RETURN THIS QUESTIONNAIRE IN THE PRE-PAID ENVELOPE.

22 November 2010

Dear ...,

RE: Chiropractic Patient-Reported Outcome Measures Study (C-PROMS)

Thank you for agreeing to participate in the above study.

Please find enclosed the following documents:

- ✓ 1 User guide
- ✓ 10 Pre-treatment questionnaires (Questionnaire 1)
- ✓ 10 Pre-paid return envelopes

The first thing you should do is carefully read about the study and how it is conducted in the User Guide. This should take you no more than 5-10 minutes. The study has been designed to cause minimal disruption to your practice. The data collection process is straightforward, but it is important that you understand the procedures we ask you to follow. If you have any questions, please feel free to contact us, either by phone or email, using the contact details given on page 3 of the User Guide. Moreover, if you require additional questionnaires or pre-paid envelopes please do not hesitate to contact the Principal Investigator.

Once you are familiar with the procedures of the study, you are ready to start. You can start at any time that is convenient to you, but once you do start you must **consecutively** recruit 10 patients who meet the eligibility criteria. It is important that you follow the instructions detailed in the User Guide so that all the data you collect are valid and complete. The credibility of this study is dependent on your efforts and diligence in this process, and for this we are very grateful.

All participating chiropractors will automatically be entered into a prize draw unless we hear from you to the contrary. The results of the draw will be announced near the end of the study.

Thank you for your time.

Yours sincerely,

Taco Houweling, DC, MRes (Principal Investigator)
Tel: 01202 436234 / 079 31444501
Email: thouweling@aecc.ac.uk

Jennifer Bolton, PhD, MA (Ed.), FCC (Hon)

David Newell, MSc, PhD

26 July 2011

Dear Sir/Madam,

RE: We need your views on chiropractic care

About three months ago you completed a questionnaire about your low back pain at the chiropractic clinic; thank you for doing so. We now ask you to complete a final follow-up questionnaire for this study. Even if you have not visited the chiropractor recently, we still need your views.

The information you provide in this questionnaire will help us improve patient care, from which you and others may benefit.

The first thing you should do is read the information and instructions on page 2 of the enclosed questionnaire. Once you have done so, you are ready to complete the questionnaire, which should take you no more than 5-10 minutes of your time.

Please do so and **return it as soon as possible in the pre-paid envelope provided.** If you would prefer to complete this questionnaire online, please go to http://www.aecc.ac.uk/research/c-proms.aspx

Thank you for your co-operation and time.

Yours faithfully,

Taco Houweling (Principal Investigator)
Tel: 01202 436234 / 079 31444501
Email: thouweling@aecc.ac.uk

Jennifer Bolton (Study Supervisor)

David Newell (Study Supervisor)

Please state below the TOTAL NUMBER OF VISITS each patient made to the clinic during the study period from the FIRST DAY THEY ATTENDED THE CLINIC (initial consultation) to the END OF THE STUDY PERIOD (INCLUSIVE).

Ref.	Patient name	Study period ends:	Total number of visits during study period (includes initial consultation visit)
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	
asdsdd	asdasdfa	asdasdf	

1 July 2011

Dear ...,

RE: Chiropractic Patient-Reported Outcome Measure Study (C-PROMS); Number of visits to the clinic

A few months ago, you participated in this study by administering questionnaires to a number of NEW low back pain patients presenting to your clinic; thank you for doing so. We now need to ask you the total number of visits (including the initial consultation visit) these new patients made to the clinic during the study period. This information can be gathered from your computer booking software.

Please fill in the enclosed form and return it in the pre-paid envelope provided as soon as possible. These data will be kept completely confidential. Please find enclosed a copy of the signed informed consent forms of the participating patients to allow you to release this information.

Thank you very much for your time and co-operation.

Kind Regards,

Taco Houweling (Principal Investigator)
Tel: 01202 436234 / 079 31444501
Email: thouweling@aecc.ac.uk

Jennifer Bolton (Study Supervisor)

David Newell (Study Supervisor)

Appendix 3: Ethics approval letter.

ANGLO-EUROPEAN
COLLEGE OF CHIROPRACTIC

RESEARCH & GRADUATE STUDIES

13-15 PARKWOOD ROAD
BOURNEMOUTH
DORSET BH5 2DF
UNITED KINGDOM

t +44 (0)1202 436200
f +44 (0)1202 436262
i www.aecc.ac.uk

14 October 2009

Dr Taco Houweling
AECC
Bournemouth

Dear Taco

Re: Development of an instrument to measure patient-reported outcomes and costs for low back painpatients in routine chiropractic practice

Thank you for submitting an application for ethics approval for conducting the above study.

The application (as attached) has now been granted approval by the AECC Research Ethics Sub-Committee.

May I take this opportunity to wish you every success in the study.

Yours sincerely

Professor J E Bolton, PhD, MA Ed, FHEA, FCC(Hon), FBCA, FEAC
Chair, AECC Research Ethics Sub-Committee

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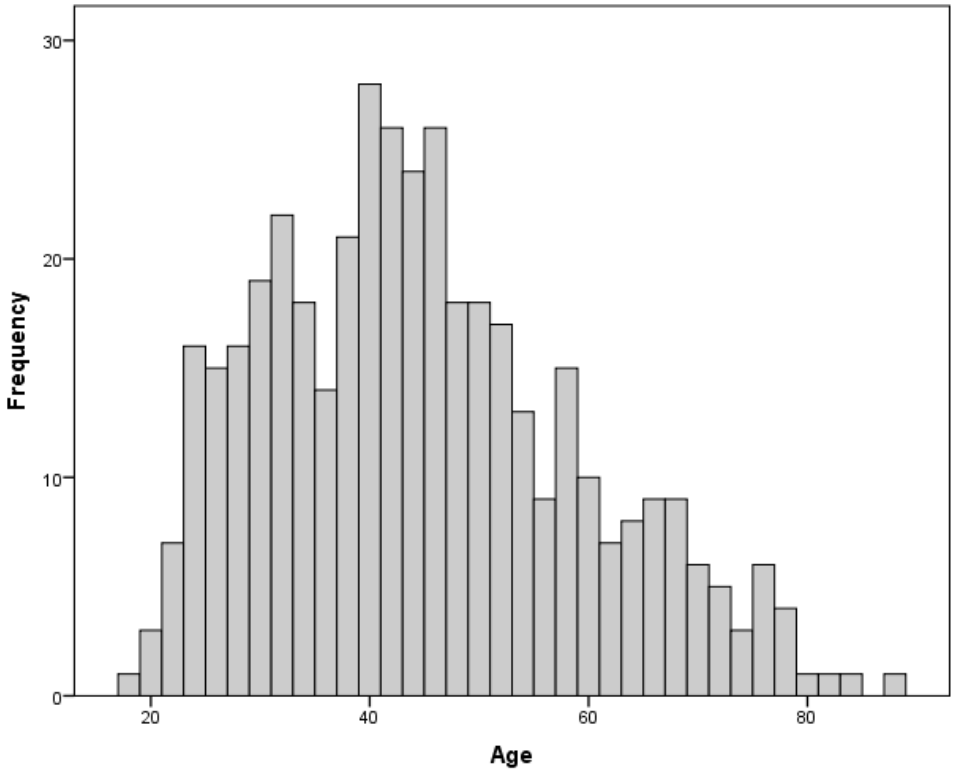
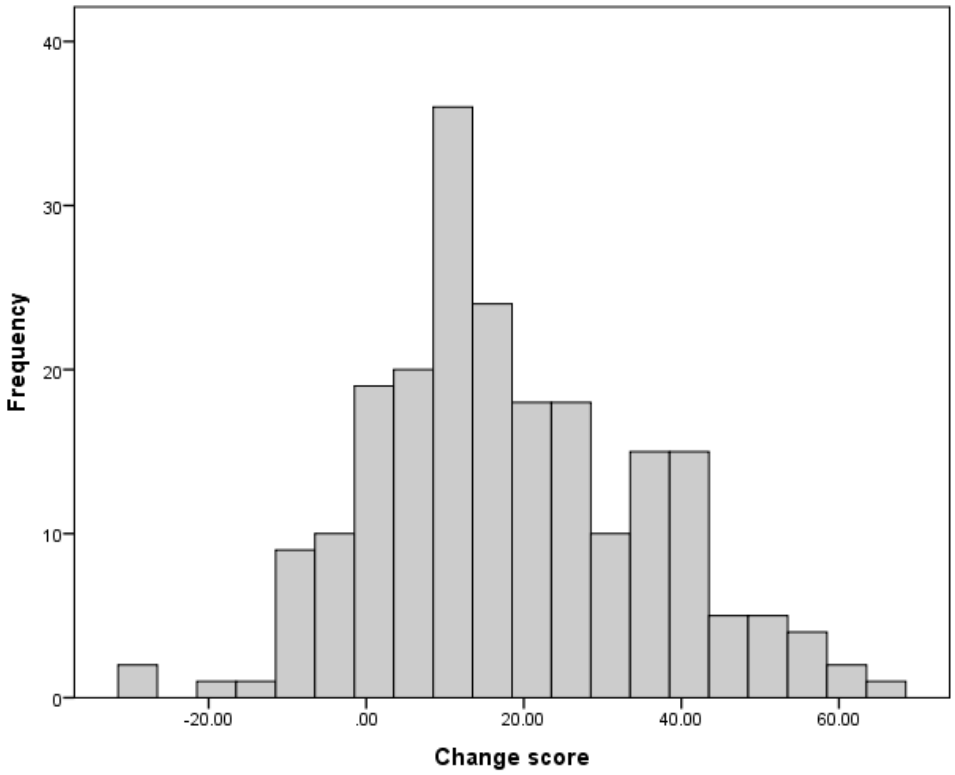
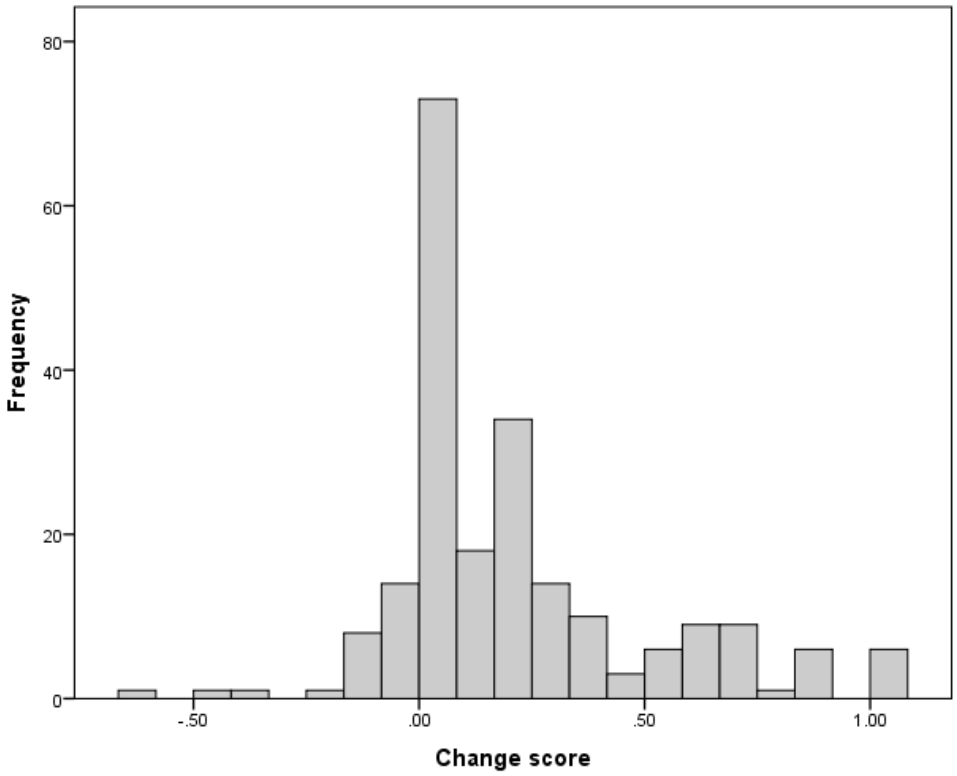
Appendix 4A: Distribution of age of patients at baseline.



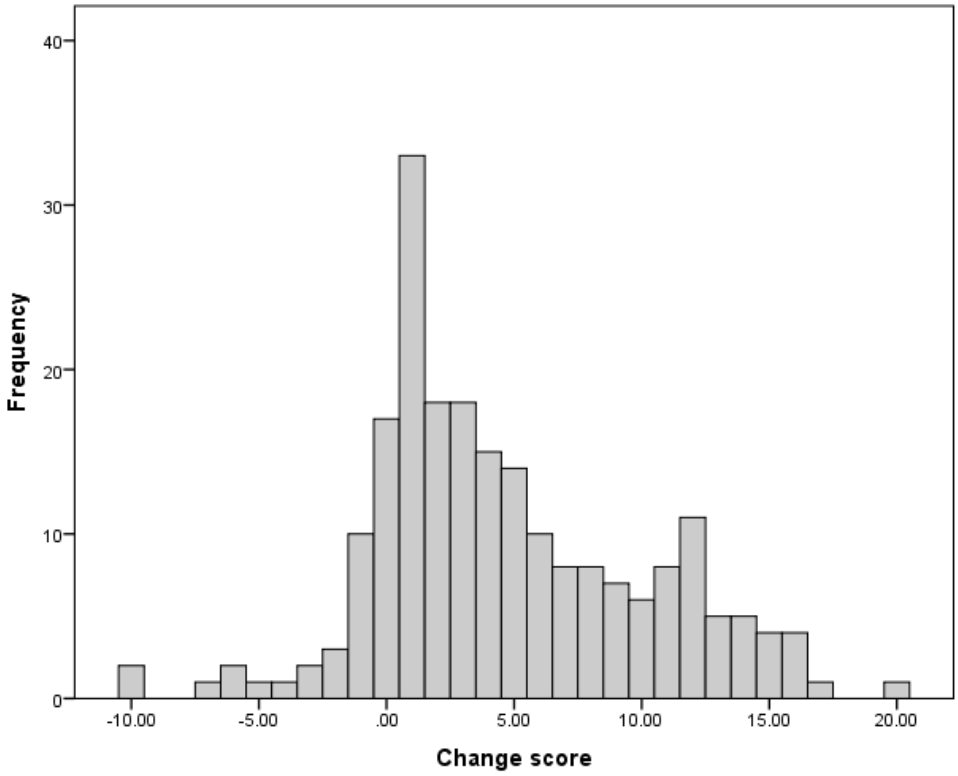
Appendix 4B: Distribution of change scores.



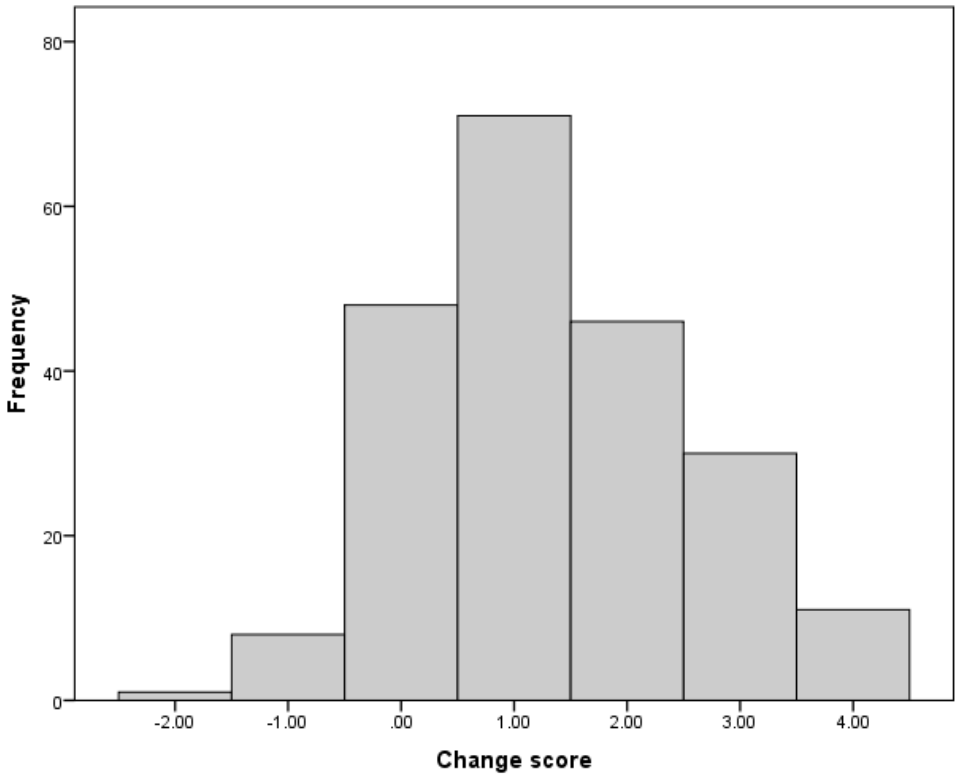
Distribution of Bournemouth Questionnaire change scores.



Distribution of EQ-5D change scores.

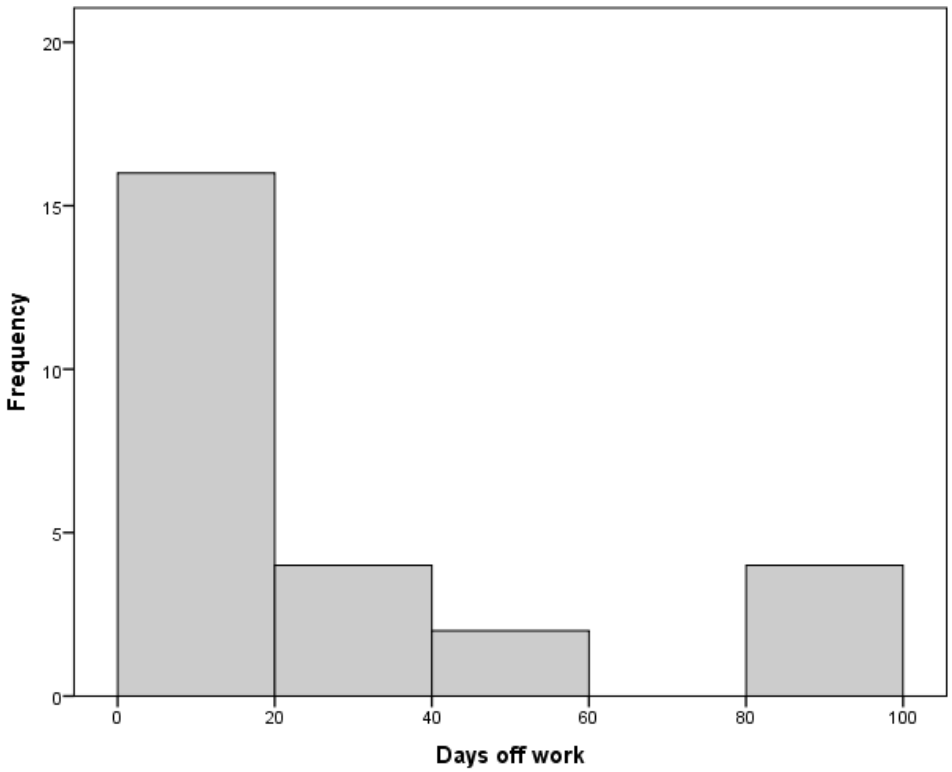


Distribution of Roland-Morris Disability Questionnaire change scores.

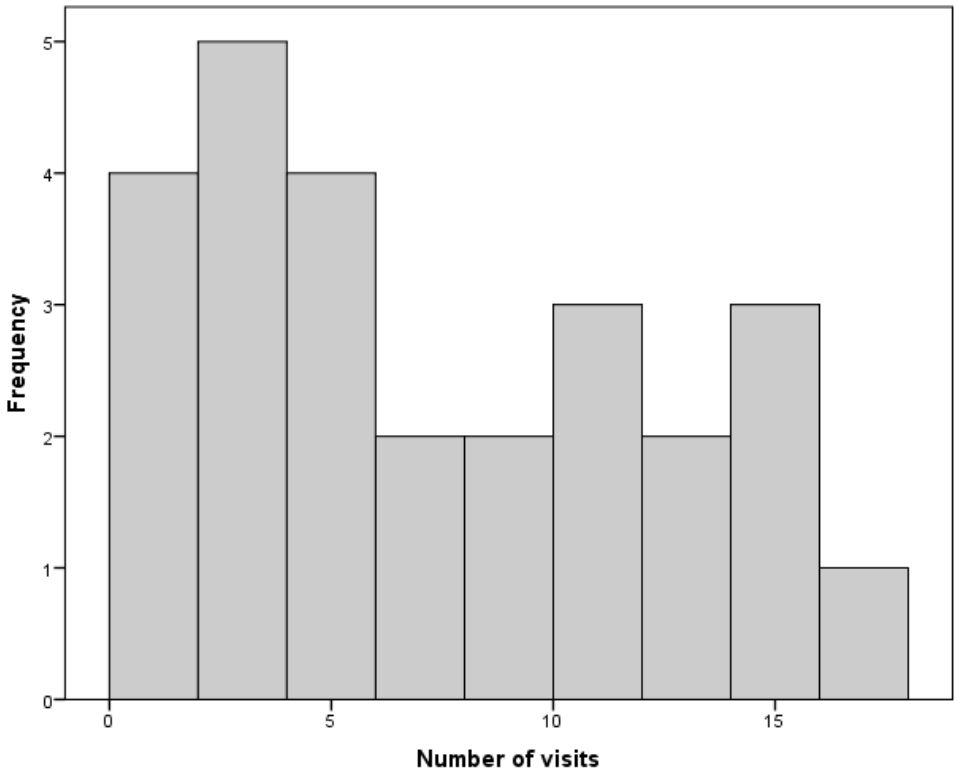


Distribution of bothersomeness scale change scores.

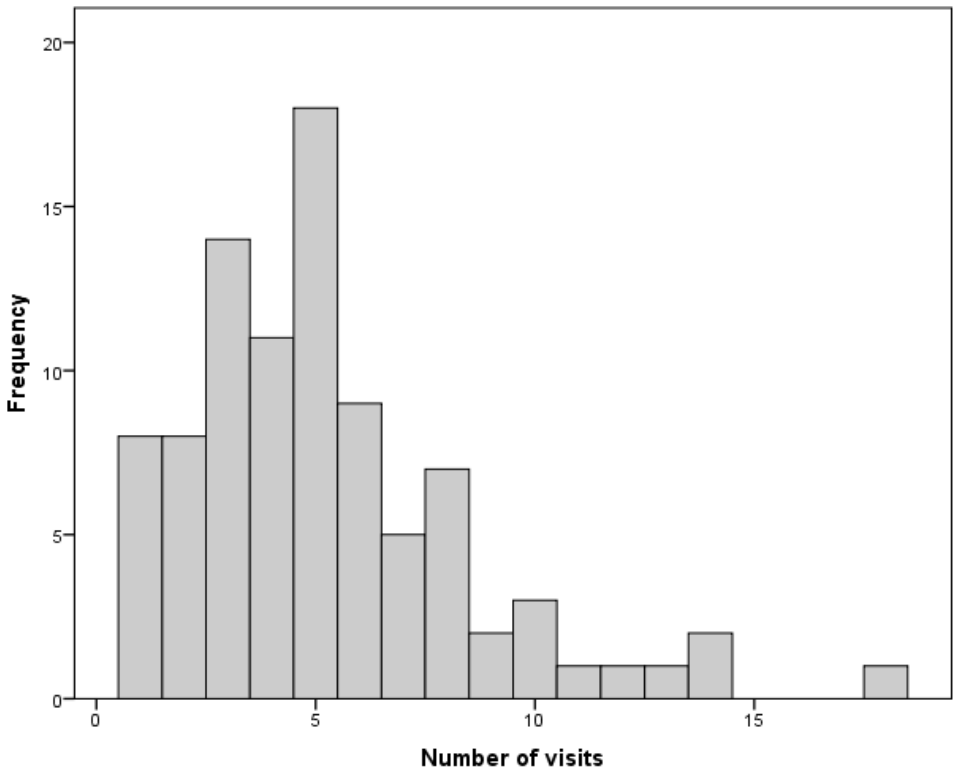
Appendix 4C: Distribution of continuous cost data.



Distribution of time off work.

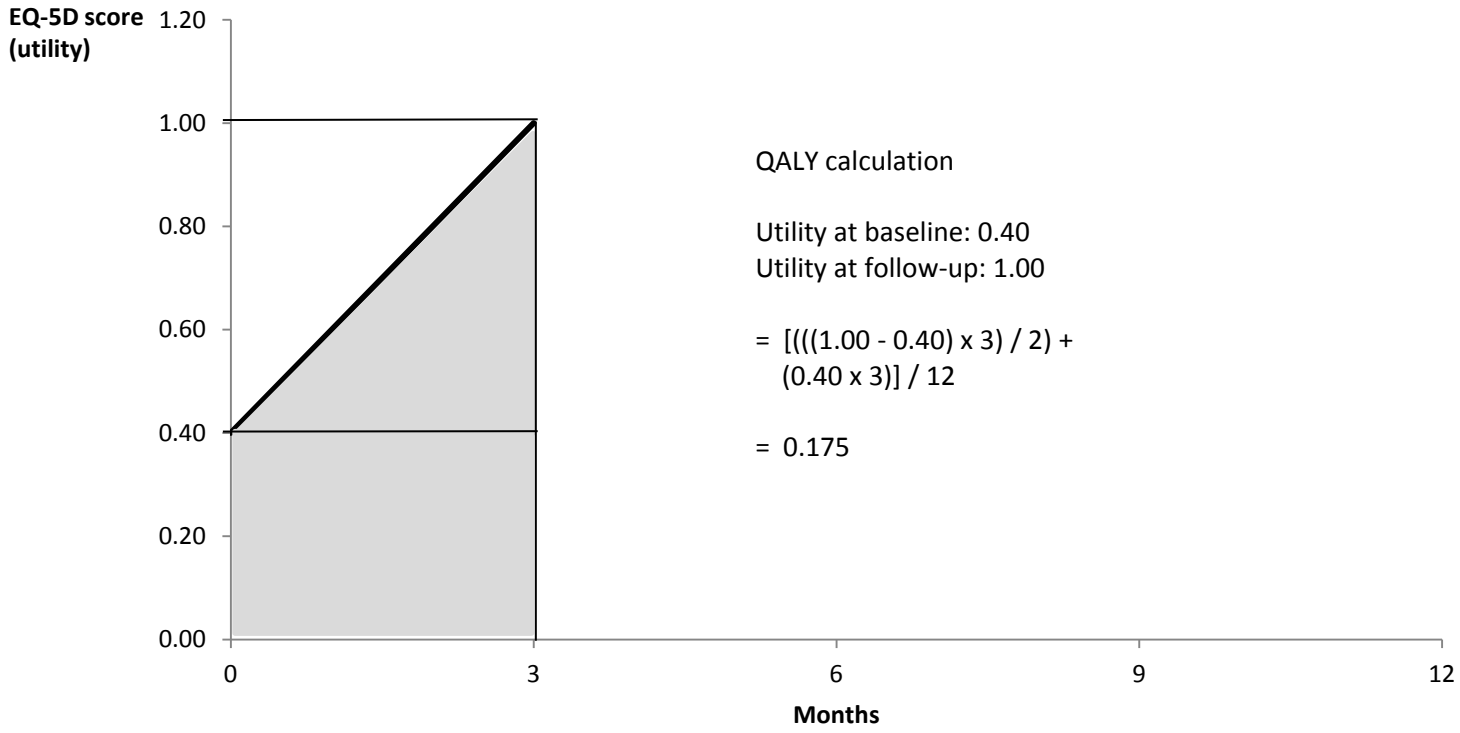


Distribution of number of chiropractic visits as reported by patients.



Distribution of number of chiropractic visits as reported in patient files.

Appendix 5: Hypothetical example of a QALY calculation assuming linear utility change over time. Grey area represents QALY over the 3-month study period.



Appendix 6: Calculation of the accuracy between dichotomous measures using sensitivity and specificity.

New measure	**External criterion (i.e. gold standard)**	
	Positive	**Negative**
Positive	True positive (TP)	False positive (FP)
Negative	False negative (FN)	True negative (TN)

Sensitivity $\frac{TP}{(TP+FN)}$

Specificity $\frac{TN}{(TN+FP)}$

Appendix 7: Unit costs.

Cost component	Unit cost (£)	Source	Details
Chiropractic	26.94	NICE costing report, 2009[238]	Cost of a visit to chiropractor adjusted for inflation (2% yearly, £25 in 2009)
GP	36.00	Unit Cost of Health and Social Care, 2011[290]	Assumes one 11.7-minute consultation
A & E	49.00	Unit Cost of Health and Social Care, 2011[290]	Cost of one visit to walk-in service
Physiotherapy	90.00	Unit Cost of Health and Social Care, 2011[290]	Assumes five 30-minute consultations. This assumption is based on the fact that low back patients receive an average of five physiotherapy sessions in the NHS.
Medical specialist	127.00	NHS reference costs, 2010-2011[291]	Consultant led first attendance
Overnight stay in hospital	549.00	Unit Cost of Health and Social Care, 2011	Mean cost per outpatient attendance (non-elective inpatient short stay)
X-Ray	67.00	NHS reference costs, 2010-2011[291]	Cost of an X-Ray (direct access)
MRI / CT Scan	162.00	NHS reference costs, 2010-2011[291]	Cost of an MRI or CT scan (one area of the body)
Injection into spine	581.80	NICE costing report, 2009[238]	Cost of spinal injection adjusted for inflation (2% yearly, £540 in 2009)
Low back surgery	9387.22	NHS study comparing surgical stabilisation to rehabilitation for low back pain, 2003[292]	Mean total cost of a surgical stabilisation operation adjusted for inflation (2% yearly, £7610 in 2003)
Cost of a day off sick	100.20	Office for National Statistics, 2011[293]	One-fifth of median weekly earnings weighted by age and gender

All NHS costs include salary, on-costs, qualifications, overhead and capital costs.

Appendix 8: Cut-off point determination using Received Operating Characteristics.

Cut-off point determination for Roland-Morris Disability Questionnaire (cut-off point in bold).

Cut-off point	Sensitivity	Specificity	*Youden's index
-11.000	1.000	0.000	0.000
-8.500	0.994	0.015	0.009
-6.500	0.994	0.030	0.024
-5.500	0.994	0.075	0.069
-4.500	0.994	0.090	0.084
-3.500	0.988	0.090	0.078
-2.500	0.988	0.119	0.107
-1.500	0.988	0.179	0.167
-0.500	0.964	0.313	0.278
0.500	0.893	0.403	0.296
1.500	0.738	0.582	0.320
2.500	0.667	0.687	0.353
3.500	0.589	0.761	0.350
4.500	**0.530**	**0.836**	**0.366**
5.500	0.458	0.881	0.339
6.500	0.387	0.881	0.268
7.500	0.339	0.881	0.220
8.500	0.304	0.925	0.229
9.500	0.262	0.925	0.187
10.500	0.238	0.955	0.193
11.500	0.196	0.985	0.182
12.500	0.131	0.985	0.116
13.500	0.095	0.985	0.080
14.500	0.071	1.000	0.071
15.500	0.042	1.000	0.042
16.500	0.018	1.000	0.018
17.500	0.012	1.000	0.012
19.000	0.006	1.000	0.006
21.000	0.000	1.000	0.000

*Younden's index (sensitivity + specificity - 1) indicates the point that maximises sensitivity and specificity.

Cut-off point determination for Bournemouth Questionnaire (cut-off point in bold).

Cut-off point	Sensitivity	Specificity	*Youden's index
-30.000	1.000	0.000	0.000
-28.000	1.000	0.016	0.016
-22.000	1.000	0.032	0.032
-15.500	1.000	0.048	0.048
-12.500	1.000	0.063	0.063
-9.500	1.000	0.111	0.111
-7.500	1.000	0.143	0.143
-6.500	0.994	0.206	0.200
-5.500	0.988	0.238	0.226
-4.500	0.982	0.238	0.220
-3.500	0.982	0.254	0.236
-2.500	0.976	0.270	0.246
-1.500	0.964	0.286	0.249
-0.500	0.964	0.317	0.281
0.500	0.933	0.365	0.298
1.500	0.921	0.365	0.286
2.500	0.903	0.413	0.316
3.500	0.897	0.429	0.326
4.500	0.867	0.444	0.311
5.500	0.848	0.460	0.309
6.500	0.836	0.492	0.328
7.500	0.806	0.492	0.298
8.500	0.788	0.540	0.328
9.500	0.770	0.587	0.357
10.500	**0.733**	**0.635**	**0.368**
11.500	0.709	0.651	0.360
12.500	0.661	0.651	0.311
13.500	0.624	0.683	0.307
14.500	0.594	0.746	0.340
15.500	0.582	0.746	0.328
16.500	0.558	0.778	0.335
17.500	0.545	0.810	0.355
18.500	0.527	0.810	0.337
19.500	0.497	0.857	0.354
20.500	0.485	0.873	0.358
22.000	0.473	0.905	0.377
23.500	0.461	0.921	0.381
24.500	0.442	0.952	0.395
25.500	0.424	0.952	0.377
26.500	0.406	0.952	0.358
27.500	0.376	0.952	0.328

28.500	0.364	0.968	0.332
30.000	0.352	0.968	0.320
31.500	0.333	0.968	0.302
32.500	0.309	0.968	0.277
33.500	0.303	0.968	0.271
34.500	0.279	0.968	0.247
35.500	0.267	0.968	0.235
36.500	0.255	0.968	0.223
37.500	0.230	0.984	0.214
38.500	0.200	0.984	0.184
39.500	0.182	0.984	0.166
40.500	0.158	0.984	0.142
41.500	0.133	0.984	0.117
42.500	0.115	1.000	0.115
43.500	0.109	1.000	0.109
44.500	0.097	1.000	0.097
45.500	0.085	1.000	0.085
47.500	0.079	1.000	0.079
49.500	0.073	1.000	0.073
50.500	0.067	1.000	0.067
52.500	0.042	1.000	0.042
54.500	0.036	1.000	0.036
55.500	0.030	1.000	0.030
57.000	0.024	1.000	0.024
59.000	0.018	1.000	0.018
61.500	0.012	1.000	0.012
63.500	0.006	1.000	0.006
65.000	0.000	1.000	0.000

*Younden's index (sensitivity + specificity - 1) indicates the point that maximises sensitivity and specificity.

Cut-off point determination for EQ-5D
(cut-off point in bold).

Cut-off point	Sensitivity	Specificity	*Youden's index
-1.661	1.000	0.000	0.000
-0.572	1.000	0.016	0.016
-0.441	1.000	0.033	0.033
-0.317	1.000	0.049	0.049
-0.220	1.000	0.066	0.066
-0.178	0.994	0.066	0.059
-0.146	0.981	0.066	0.046
-0.129	0.981	0.082	0.063
-0.111	0.975	0.082	0.056
-0.105	0.975	0.098	0.073
-0.088	0.968	0.131	0.099
-0.070	0.962	0.164	0.126
-0.062	0.949	0.230	0.179
-0.045	0.949	0.246	0.195
-0.036	0.949	0.262	0.211
-0.034	0.943	0.262	0.205
-0.017	0.936	0.279	0.215
0.006	0.758	0.492	0.250
0.022	0.758	0.508	0.266
0.033	0.758	0.525	0.283
0.035	0.752	0.525	0.276
0.044	0.701	0.607	0.307
0.053	0.694	0.607	0.301
0.056	0.688	0.607	0.294
0.063	0.688	0.623	0.311
0.070	0.656	0.721	0.377
0.072	0.643	0.754	0.397
0.080	0.643	0.770	0.414
0.096	0.637	0.770	0.407
0.105	0.637	0.787	0.424
0.106	0.605	0.803	0.408
0.124	0.599	0.820	0.418
0.140	**0.586**	**0.852**	**0.438**
0.146	0.580	0.852	0.432
0.156	0.573	0.852	0.426
0.166	0.567	0.852	0.419
0.175	0.561	0.869	0.429
0.181	0.548	0.869	0.417
0.189	0.541	0.869	0.410
0.198	0.529	0.869	0.398
0.207	0.465	0.885	0.350
0.225	0.459	0.885	0.344

0.258	0.363	0.885	0.248
0.292	0.338	0.885	0.223
0.310	0.306	0.885	0.191
0.319	0.287	0.885	0.172
0.327	0.287	0.885	0.172
0.347	0.274	0.885	0.159
0.374	0.268	0.885	0.153
0.389	0.229	0.885	0.115
0.406	0.229	0.902	0.131
0.438	0.217	0.902	0.118
0.474	0.210	0.902	0.112
0.502	0.197	0.902	0.099
0.526	0.191	0.902	0.093
0.532	0.191	0.902	0.093
0.550	0.185	0.934	0.119
0.568	0.178	0.934	0.113
0.579	0.178	0.951	0.129
0.599	0.172	0.951	0.123
0.622	0.166	0.951	0.116
0.637	0.153	0.967	0.120
0.638	0.140	0.967	0.107
0.649	0.140	0.984	0.124
0.666	0.134	0.984	0.117
0.672	0.134	1.000	0.134
0.681	0.127	1.000	0.127
0.691	0.121	1.000	0.121
0.714	0.115	1.000	0.115
0.738	0.102	1.000	0.102
0.741	0.096	1.000	0.096
0.785	0.083	1.000	0.083
0.835	0.076	1.000	0.076
0.842	0.064	1.000	0.064
0.848	0.057	1.000	0.057
0.865	0.051	1.000	0.051
0.894	0.045	1.000	0.045
0.964	0.038	1.000	0.038
1.045	0.006	1.000	0.006
2.074	0.000	1.000	0.000

*Younden's index (sensitivity + specificity - 1) indicates the point that maximises sensitivity and specificity.

Cut-off point determination for bothersomeness scale (cut-off point in bold).

Cut-off point	Sensitivity	Specificity	*Youden's index
-3.000	1.000	0.000	0.000
-1.500	1.000	0.015	0.015
-0.500	0.994	0.152	0.146
0.500	0.827	0.500	0.327
1.500	**0.524**	**0.909**	**0.433**
2.500	0.256	1.000	0.256
3.500	0.071	1.000	0.071
5.000	0.000	1.000	0.000

*Younden's index (sensitivity + specificity - 1) indicates the point that maximises sensitivity and specificity.

Appendix 9: Comparative analysis between the follow-up cohort and the validation sample. No significant differences were found.

Variable		Follow-up cohort (n = 238)	Sample cohort (n = 89)
Age	Mean (SD, range) number of years	47.3 (14.45, 19-88)	46.3 (14.46, 19-88)
	Missing	2	1
Gender	Male	104 (44)	40 (45)
	Female	134 (56)	49 (55)
	Missing	0	0
Work status	In paid (including self) employment	183 (77)	71 (80)
	At home and not looking for work	8 (3)	2 (2)
	Unemployed because of back pain	1 (< 1)	0
	Unemployed because of other reasons	7 (3)	3 (3)
	Retired	35 (15)	10 (11)
	Student	4 (2)	3 (3)
	Missing	0	0
Pain history	< 3 months	84 (35)	29 (33)
	3-6 months	37 (16)	13 (15)
	7-12 months	29 (12)	14 (16)
	1-2 years	29 (12)	13 (15)
	3-5 years	23 (10)	7 (8)
	6-10 years	14 (6)	5 (6)
	> 10 years	21 (9)	7 (8)
	Missing	1 (< 1)	1 (< 1)
Medication usage	Never	50 (21)	23 (26)
	Rarely	53 (22)	23 (26)
	Sometimes	83 (35)	26 (29)
	Every day	52 (22)	17 (19)
	Missing	0	0

Values are frequency (%) unless stated otherwise. N = number of observations. Statistical significance ($p < 0.05$) determined using chi^2 test for categorical and independent t-test for continuous variables.

Appendix 9 *(continued)*: Comparative analysis between the follow-up cohort and the validation sample. No significant differences were found.

Variable		Follow-up cohort (n = 238)	Sample cohort (n = 89)
RMDQ	Mean (SD) score	7.4 (5.13)	7.4 (5.14)
	Missing	0	0
BQ	Mean (SD) score	29.4 (15.41)	29.2 (15.65)
	Missing	5	2
EQ-5D	Mean (SD) score	0.59 (0.27)	0.62 (0.26)
	Missing	10	4
Bothersomeness scale	Mean (SD) score	3.5 (0.96)	3.5 (0.93)
	Missing	0	0

RMDQ = Roland-Morris Disability Questionnaire. BQ = Bournemouth Questionnaire.
EQ-5D = EuroQol-5D.